PB83-130302

Chemical Substances Designation
Volume II: EPA

ICF, Inc.
Washington, DC

Prepared for

Environmental Protection Agency
Washington, DC

Dec 81

U.S. Department of Commerce
National Technical Information Service
NTIS

REPORT DOCUMENTATION PAGE

1. REPORT NO. EPA - 560/TIIS-82-004

2.

3. Recipient's Accession No. PB83 130302

4. Title and Subtitle

Chemical Substances Designation
Volume II: EPA

5. Report Date December 1981

6.

7. Author(s) Bailey, et al

8. Performing Organization Rept. No.

9. Performing Organization Name and Address

ICF Incorporated
1850 K Street, N. W.
Washington, D. C. 20006

10. Project/Task/Work Unit No.

11. Contract(C) or Grant(G) No.
(C) 68-01-6038
(G)

12. Sponsoring Organization Name and Address

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Toxics Integration
Washington, D. C. 20460

13. Type of Report & Period Covered Informational

14.

15. Supplementary Notes

16. Abstract (Limit: 200 words)

This volume, part of a four volume study, examines EPA and other Federal agencies statutory and regulatory criteria for the designation of chemical substances. Volume I, a comparative analysis of the statutory authorities described in Volumes II and III, focuses on statutory purposes and goals, integration directives, the risks to be regulated, and the factors considered for designating and regulating chemical substances. The designation of chemical substances for regulation, hazard classifications and testing requirements are compared in the last section of Volume I. Volumes II and III review statutory provisions and regulations relating to the EPA and other Federal agency designation of chemical substances. The reviews focus on the criteria used to designate chemicals for regulation (e.g. role of economic and technological factors). The reviews specify which chemical substances are designated for regulation and each volume describe and analyze the hazard classification systems established and corresponding test methods required by the regulations. Volume IV, the chemical designation matrix provides a listing of the substances designated by regulation under the statues reviewed as they appear in the Code of Federal Regulations or the Federal Register (for proposed rules) as of January 1981.

17. Document Analysis a. Descriptors

b. Identifiers/Open-Ended Terms

c. COSATI Field/Group

18. Availability Statement

19. Security Class (This Report)

20. Security Class (This Page)

21. No. of Pages

22. Price

(See ANSI-Z39.18)

See Instructions on Reverse

OPTIONAL FORM 272 (4-77)
(Formerly NTIS-35)
Department of Commerce

PB83-130302

TOXICS INTEGRATION POLICY SERIES EPA 560/TIIS-82-004

CHEMICAL SUBSTANCES DESIGNATION

VOLUME 2:

EPA

Project Officer:

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Prepared under Contract No: 68-01-6038 for the

Office of Toxics Integration
Office of Pesticides and Toxic Substances
Environmental Protection Agency
December 1981

REPRODUCED BY
NATIONAL TECHNICAL
INFORMATION SERVICE
U.S. DEPARTMENT OF COMMERCE
SPRINGFIELD, VA 22161

DISCLAIMER

The information included in this report include regulations or policies that were proposed or promulgated as of January 1, 1981 by the U.S. Environmental Protection Agency and other federal agencies. Because the regulations and policies described are subject to differing interpretations and their status may have changed since January 1, 1981, the reader is cautioned to view the materials in this light. In addition, this report is not intended to be a comprehensive up-to-date listing of all regulations or policies, but rather should be used to retrospectively understand how agencies designate chemical substances. The contents of this report were prepared under contract to EPA and, though reviewed by EPA and other agency staff, this review does not necessarily reflect the views and policies of the U.S. Environmental Protection Agency nor those of the other federal agencies whose authorities and regulations are reviewed.

Foreword

A major factor that contributes to integration of EPA as well as interagency activities on chemicals is understanding the purposes and major objectives that must be considered by each statute when designating chemicals for regulation. Because of the numerous statutes and regulations with differing purposes that designate hazardous materials, wastes or substances and toxic pollutants or substances, confusion often results.

The purpose of this four volume study is to lay out the key factors required by the statutes and their implementing regulations that must be considered when designating chemicals. The document serves as a ready reference to those faced with designing as well as complying with federal regulatory actions regarding chemicals.

Walter W. Kovalick Jr

Walter W. Kovalick, Jr.
Director
Integration Staff

PREFACE

Volume 2 reviews the statutory provisions and regulations relating to the Environmental Protection Agency's designation of chemical substances. The following EPA authorities are included:

Toxic Substances Control Act

Federal Water Pollution Control Act

Safe Drinking Water Act

Marine Protection, Research, and Sanctuaries Act

Resource Conservation and Recovery Act

Federal Insecticide, Fungicide, and Rodenticide Act

Clean Air Act

Comprehensive Environmental Response, Compensation and Liability Act of 1980

The statutory and regulatory reviews are current as of January 1, 1981.

The statutes are examined to determine the mandates and/or authority for EPA to designate chemicals as hazardous or toxic substances. Relevant legislative history, court cases, and settlements are reviewed to clarify the legal basis and rationale for statutory provisions. In addition, the chemical substances covered by the statutes are specified, the statutory definitions of "hazardous" and "toxic" substances are detailed, the statutory criteria for designating chemicals for regulation are analyzed, the types of hazards addressed in the statute are identified, and the statutory bases for regulatory action are presented.

Regulations that relate to the designation of hazardous or toxic substances and are promulgated or proposed under the statutes listed above are also reviewed. Regulatory reviews focus on the criteria used by EPA to designate chemicals for regulation and the chemicals so designated. This entails examining chemical definitions, test methods, specific chemical concentrations which trigger regulatory provisions, as well as health and welfare effects and regulatory assumptions which are cited as the basis for designating a chemical.

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TOXIC SUBSTANCES CONTROL ACT--STATUTORY REVIEW

The Toxic Substances Control Act (TSCA)[1] authorizes the EPA to regulate "chemical substances and mixtures." The Act states:

> It is the policy of the United States that adequate authority should exist to regulate chemical substances and mixtures which present an unreasonable risk of injury to health or the environment, and to take action with respect to chemical substances and mixtures which are an imminent hazard . . . [Section 2(b)(2)]

The following discussion focuses on five elements of TSCA:

- What kind of agency regulation is authorized or required?
- To what activity and/or subject matter is the action directed?
- What kind of harm is sought to be avoided?
- What level of causality must exist between this activity/subject matter and the harm involved?
- What criteria or factors must be taken into consideration before the action is taken?

There is little case law directly relevant to this discussion. Explanatory comments, therefore, rely primarily on TSCA's legislative history.

INTRODUCTION

Under TSCA, EPA is required (i.e., mandated) or authorized (i.e., permitted) to take a variety of regulatory actions regarding chemical substances and mixtures. Those actions include requirements for testing and data submission, prohibition or limitation of activities involving chemical substances and mixtures, and imposition of reporting and recordkeeping requirements. EPA also is given authority to develop lists of chemical substances or mixtures that are to be given special regulatory treatment.

---

[1] 15 USC §§ 2601-2629).

The subject matter with which TSCA is concerned, as noted above, is "chemical substances and mixtures."[2] In a few instances, the subject matter is extended to include "articles" containing the chemical substances or mixture, as well as "categories of chemical substances or mixtures."[3] All regulatory actions authorized or required to be taken by EPA with respect to a chemical substance or mixture are applicable also to "categories of chemical substances or mixtures" (Section 26(c)).

It is specific activities or risks or combinations of activities and risks involving chemical substances and mixtures that trigger TSCA requirements. In particular, the specific activities are the manufacture (defined in Section 3(7)), distribution in commerce (defined in Section 3(4)), processing (defined in Section 3(10)), use, or disposal of chemical substances and mixtures, or any combination of these activities.

The kind of harm most often addressed by TSCA is termed "an unreasonable risk of injury to health or the environment." "Unreasonable risk" is not defined in TSCA. The House Report indicates the following reason for this intentional omission:

---

[2] "Chemical substance" is defined (Section 3(2)) to mean "any organic or inorganic substance of a particular molecular identity. . . ." This includes combinations of organic and inorganic substances that are wholly or partially the result of a chemical reaction or which occur in nature. The definition also includes "any element or uncombined radical." Some items are specifically excluded from the definition, including mixtures, pesticides, tobacco, and nuclear material.

"Mixture" is defined (Section 3(8)) as "any combination" of chemical substances if that combination is not naturally occurring or not in part or in whole the result of a chemical reaction. However, reaction-produced combinations are included in the definition of mixture if they are not comprised of any new chemical substances and if such a combination could have been produced without a chemical reaction. The reason for this exception is "to prevent disparate treatment of identical combinations simply because of the number of steps used in the manufacture of the combination." (Legislative History, p. 670.)

[3] "Category of chemical substances" is defined (Section 26 (c)(2)(A)) to mean "a group of chemical substances the members of which are similar in molecular structure, in physical, chemical, or biological properties, in use, or in mode of entrance into the human body or into the environment, or the members of which are in some other way suitable for classification as such for purposes of this Act, except that such term does not mean a group of chemical substances which are grouped together solely on the basis of their being new chemical substances."

"Category of mixtures" is defined (Section 26(c)(2)(B)) to mean "a group of mixtures the members of which are similar in molecular structure, in physical, chemical, or biological properties, in use, or in the mode of entrance into the human body or into the environment, or the members of which are in some other way suitable for classification as such for purposes of this Act."

> [T]he determination of unreasonable risk involves a consideration of probability, severity, and similar factors which cannot be defined in precise terms and is not a factual determination but rather requires the exercise of judgment on the part of the person making it. . . . [Legislative History, pp. 421-422]

More specifically, the House Report indicated what factors should generally be weighed in making the determination that an unreasonable risk exists. Such a determination involves

> balancing the probability that harm will occur and the magnitude and severity of that harm against the effect of proposed regulatory action on the availability to society of the benefits of the substance or mixture, taking into account the availability of substitutes for the substance or mixture which do not require regulations and other adverse effects which such proposed action may have on society. [Legislative History, p. 422]

Thus, "unreasonable risk" is not a uniform or rigid concept. The House Report states that

> [a]lthough the standard for defining the regulatory authority of [EPA] . . . throughout the bill is "unreasonable risk," the implementation of the standard will of necessity vary depending on the specific regulatory authority which [EPA] . . . seeks to exercise. [Legislative History, p. 422]

In practical terms this suggests that the less negative impact a regulatory action by EPA will have, the easier it will be for EPA to make the determination that there is an unreasonable risk. Other formulations of harm to health and the environment are mentioned in individual situations, but none is as pervasive as "unreasonable risk." Those other formulations will be discussed as appropriate.

The level of causality required to trigger agency action varies, but one formulation is used most frequently: "presents an unreasonable risk." The conference committee selected the term "presents" and rejected the phrase "cause or significantly contribute to . . ." The intention of the conferees in selecting the term "presents" was

> that [EPA] . . . be able to address substances and mixtures which indirectly present unreasonable risks, as well as those which directly present such risks. Further, the conferees do not intend that a substance or mixture must be the single factor which results in the presentation of the risk. [Legislative History, p. 673]

There are other levels of causation that are required for specific regulatory actions, but "presents" is the most frequently used. The other formulations for causation will be discussed as appropriate.

Section 2(c) of TSCA sets out the general factors that EPA is to consider in administering the Act. EPA "shall carry out this Act in a reasonable and prudent manner, and . . . shall consider the environmental, economic, and social impact of any action [EPA] . . . takes or proposes to take under this Act." This suggests that TSCA regulatory actions are to involve some balancing of costs and benefits. However, a formal cost benefit analysis is not required. The House Report indicates

> that the bill is not to be construed as a direction to [EPA] . . . to make any statement of findings in addition to those required by specific provisions of the bill or to involve [EPA] . . . in any cost-benefit justifications. [Legislative History, p. 471]

Exhibit 1-1 summarizes TSCA's approach to the regulation of chemical substances and mixtures which pose some level of harm to health or the environment. As noted above, the phrase "unreasonable risk of injury" is used frequently, but may have different meanings in different situations. The exhibit below indicates what these differences are in the column that summarizes what criteria must be met before action is taken. It will be obvious that the criteria for the different actions will vary considerably even though the harm involved in each is an "unreasonable risk of injury." Each entry in the exhibit receives detailed attention in the discussion immediately following.

There are many individual situations where TSCA authorizes or requires agency action. These situations are discussed below in terms of the five elements just outlined. The specific discussion focuses on Sections 4-8 of the Act, which set out most of the actions necessary to address risks posed by chemical substances and mixtures. Unless otherwise noted, all section references are to the Act.

EXHIBIT 1-1

OVERVIEW OF TSCA'S REGULATORY APPROACH

REGULATORY ACTION INVOLVED	KIND OF HARM TO BE AVOIDED	LEVEL OF CAUSALITY	FACTORS TO BE CONSIDERED
1. Section 4(a): Chemical substances and mixtures testing rules	• Unreasonable risk of injury to health or the environment	• "May present" an unreasonable risk or • Lack of information makes it impossible to say whether it "may present" an unreasonable risk • Substantial quantities are or will be produced and there is or may be (1) substantial human exposure, or (2) substantial environmental pressure	• Data from required tests must be "relevant" to determination that unreasonable risk is or is not presented • "Relative costs" of test protocols and methods that may be required • Reasonably foreseeable availability of personnel and facilities for conducting the required testing
2. Section 4(f): Take appropriate action under sections 5, 6, or 7 (e.g., promulgate a rule under Section 6(a) to prohibit the manufacture of a chemical substance or mixture)	• Significant risk of serious or widespread harm to humans from cancer, gene mutations, or birth defects	• "Presents or will present" a significant risk	• Reasonable basis to conclude that the requisite harm and causality exist • Action taken must reduce to a "sufficient extent" the risks involved • If the risk presented is not "unreasonable," no action need be taken by EPA
3. Section 5(b)(4)(A), and (b)(2): Compile list of chemical substances for which certain data concerning risk must be supplied to EPA	• Unreasonable risk of injury to health or the environment	• "Presents or may present" an unreasonable risk	• All "relevant factors" including the effects of the chemical substance on health and environment, and the magnitude of exposure to humans and the environment
4. Section 5(e): Pending development of further information, limit or prohibit manufacture, processing, distribution in commerce, use, or disposal of a chemical substance for which a premanufacturing notice must be submitted.	• Unreasonable risk of injury to health or the environment • Significant or substantial exposure of humans and environment	• "May present" an unreasonable risk • Substantial environmental exposure occurs or "may reasonably be anticipated" to occur and significant or substantial human exposure occurs or "may" occur	• There must be insufficient information to make a "reasonable evaluation" of the chemical's effect on humans and the environment • EPA determines, in the absence of necessary information, that the harm may occur

EXHIBIT 1-1

SUMMARY OF TSCA'S REGULATORY APPROACH
(Continued)

REGULATORY ACTION INVOLVED	KIND OF HARM TO BE AVOIDED	LEVEL OF CAUSALITY	FACTORS TO BE CONSIDERED
5. Section 5(f): Issue proposed section 6(a) rule, to be effective on publication, to limit manufacture, processing, distribution in commerce, use, or disposal of a chemical substance for which a premanufacturing notice must be submitted, or any combination of these activities or Issue a proposed order or seek an injunction to prohibit the manufacture, processing, or distribution in commerce of a chemical substance for which a premanufacturing notice must be submitted	• Unreasonable risk of injury to health or the environment	• "Presents or will present" an unreasonable risk	• "Reasonable basis" for concluding that an unreasonable risk is involved with a chemical for which a premanufacturing notice must be submitted • Unreasonable risk of injury is presented or will be presented before a section 6 rule can guard against it
6. Section 6(a): Prohibit or limit by rule the manufacture, processing, distribution in commerce, use, or disposal of chemical substances, or mixtures, or any combination of these activities	• Unreasonable risk of injury to health or the environment	• "Presents or will present" an unreasonable risk	• "Reasonable basis" for concluding the risk exists • Agency action must protect "adequately" against the risk • Agency action must impose the "least burdensome requirement" • EPA must make and publish a list of explicit considerations: - effects of the chemical on health and the environment - magnitude of human and environmental exposure - benefits of the chemical and available substitutes - "reasonably ascertainable economic consequences" of action taken

EXHIBIT 1-1

SUMMARY OF TSCA'S REGULATORY APPROACH
(Continued)

REGULATORY ACTION INVOLVED	KIND OF HARM TO BE AVOIDED	LEVEL OF CAUSALITY	FACTORS TO BE CONSIDERED
6. Section 6(a): (continued)			• Consider overlap with other legislation - "all relevant aspects of the risk" - comparison of estimated compliance costs - comparison of "relative efficiency"
7. Section 6(b): Require submission of quality control plans; order revisions in such plans, require that notice be given, and require that replacement or refund be given	• Unreasonable risk of injury to health or the environment	• The manner in which manufacturing or processing is done "unintentionally causes the chemical . . . to present or . . . will cause it to present" an unreasonable risk	• "Reasonable basis" for concluding that the manufacturing or processing will unintentionally cause the risk to be presented • Determination that quality control procedures are inadequate must be based on record after a hearing that conforms with the Administrative Procedures Act
8. Section 6(d)(2): Make a proposed section 6(a) rule effective immediately upon publication in the Federal Register	• Unreasonable risk of serious or widespread injury to health or the environment	• Manufacturing, processing distribution in commerce, use, disposal, or any combination of these activities is "likely to result" in unreasonable risk	• Unreasonable risk is likely to occur before the date when the promulgated rule becomes final, and the public interest requires an earlier effective date
9. Section 6(e): Broad regulatory control over PCBs including authority to exempt some persons from statutory prohibitions	• Unreasonable risk of injury to health or the environment	• Unreasonable risk "would not result"	• Finding that unreasonable risk will not result • Petitioner for exemption has made an unsuccessful but good faith effort to find a safe substitute
10. Section 7(a): Authority to bring suit to seize chemical substance or mixture and/or appropriate relief against a person manufacturing, distributing in commerce, using or disposing this chemical or an article containing it	• Imminent and unreasonable risk of serious or widespread injury to health or environment	• "Presents" the risk addressed	• Federal court must determine that activities involving the chemical in question present an imminent hazard

EXHIBIT 1-1

SUMMARY OF TSCA'S REGULATORY APPROACH
(Continued)

REGULATORY ACTION INVOLVED	KIND OF HARM TO BE AVOIDED	LEVEL OF CAUSALITY	FACTORS TO BE CONSIDERED
11. Section 8(c): Define what is a "significant adverse reaction" for which records must be kept by persons who manufacture, process, or distribute in commerce a chemical substance or mixture	• Significant adverse reaction	• Reactions "alleged to have been caused" by the chemical	• Seriousness, frequency, and duration of the reactions
12. Section 8(e): Report certain information to EPA if person manufactures, processes, or distributes in commerce a chemical substance or mixture	• Substantial risk of injury to health or the environment	• "Presents" the risk of harm	• Information must be reported if it "reasonably supports" the conclusion that a substantial risk of injury exists • Report is unnecessary if person has "actual knowledge" that EPA has been adequately informed

ACTION UNDER SECTION 4(a)

Under two circumstances, EPA is directed to require by rule that chemical substances or mixtures be tested (4(a)(1)). First, if EPA finds that:

- the manufacture, processing, distribution in commerce, use, or disposal of the substance or mixture, or any combination of these activities may present an unreasonable risk of injury to health or the environment;
- there is insufficient data and experience to make a reasonable determination or prediction of the health and environmental effects of the substance or mixture; and
- testing is needed to provide sufficient data;

then testing must be required (4(a)(1)(A)). Alternatively, if EPA finds that:

- a chemical substance or mixture is produced in substantial quantities and it enters the environment in substantial quantities or there is substantial or significant human exposure to the chemical;
- there is insufficient data and experience to make a reasonable determination or prediction of the health and environmental effects of the substance or mixture; and
- testing is needed to develop this information;

then testing must be required (4(a)(1)(B)).

The kind of harm sought to be avoided is the same under both alternatives: "an unreasonable risk of injury to health or the environment." The general meaning of this phrase was discussed above. By using it in Section 4(a)(1)(A), the conference committee indicated an intention

> to focus [EPA's] . . . attention on those chemical substances and mixtures about which there is a basis for concern, but about which there is inadequate information to reasonably predict or determine their effects on health or the environment. [EPA] . . . need not show that the substance or mixture does or will present a risk. [Legislative History, p. 674]

As the conferees noted, "there are certain situations in which testing should be conducted even though there is an absence of information indicating that the substance or mixture *per se* may be hazardous." (Legislative History, *id*.)

The level of causality that must exist between the chemical substance (or mixture) and the unreasonable risk of injury. The testing requirement must be imposed if the chemical "may present" the unreasonable risk. The use and meaning of "presents" was discussed earlier. The use of the conditional "may" reflects Congress' intent (illustrated in the passages just quoted) that this requirement can be triggered even when there is uncertainty about the health and environmental effects of a chemical.

The legislative history of "may present" in Section 4 is quite interesting. The Toxic Substances Control Act of 1975, H.R. 7664, which was not enacted, authorized a testing rule when "necessary to protect against" unreasonable risk to health or the environment.[4] The House Committee the next year adopted, instead, the words "may cause or significantly contribute to" an unreasonable risk. The members of the Committee reasoned that if action were "necessary to protect against unreasonable risk to health or the environment," presumably EPA would take action under Section 6.[5]

The House Report briefly discusses the choice of the word "may."

> It should be noted that the bill does not require the Administrator to find that a substance or mixture does cause or significantly contribute to or will cause or significantly contribute to an unreasonable risk. Such a finding requirement would defeat the purpose of the section, for if the Administrator is able to make such a determination, regulatory action to protect against the risk, not additional testing, is called for. However, the term "may" as used in the phrase "may cause or significantly contribute to" does not permit the Administrator to make a finding respecting probability of a risk on the basis of mere conjecture or speculation, i.e., it may or may not cause a risk. [Legislative History, pp. 424-5]

Ultimately, though, the conference committee adopted the Senate language "may present" in lieu of "may cause or significantly contribute to." In choosing this term, the conferees intended

> that [EPA] . . . be able to address substances and mixtures which indirectly present unreasonable risks, as well as those which directly present such risks. Further, the conferees do not intend that a substance or mixture must be the single factor which results in the presentation of the risk.

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[4] Legislative History, p. 489.

[5] Ibid.

> Oftentimes an unreasonable risk will be presented because of the interrelationship or cumulative impact of a number of different substances or mixtures. The conferees intend that the Administrator have authority to protect health and the environment in such situations. [Legislative History, pp. 673-4.]

The criteria or factors to be considered in requiring testing: Section 4(b) details required considerations for setting rules to govern testing. Development of the testing rules must include consideration of "the relative costs of the . . . test protocols and methodologies which may be required under the rule and the reasonably foreseeable availability of the facilities and personnel" necessary for the testing required by the rule (4(b)(1)).

Although this suggests that TSCA regulatory actions are to involve some moderation and balancing, the House Report specifically states that the determination of unreasonable risk under Section 4(a):

> . . . does not require a formal benefit-cost analysis under which a monetary value is assigned to the risks associated with a substance and to the cost to society of proposed regulatory action on the availability of such benefits. Because a monetary value often cannot be assigned to a benefit or cost, such an analysis would not be very useful. [Legislative History, p. 422]

It is interesting to note that under Section 4(a) of the Senate Committee bill, S.3149, the Administrator was specifically instructed to "consider the reasonably ascertainable costs and other burdens associated with conducting such tests in light of the possible risks of injury to health or the environment and . . . [to] publish the same in the Federal Register." This requirement, however, was not included in the final TSCA that emerged from the Conference Committee.

Finally, "unreasonable risk" is not to be construed as a uniform or rigid concept. The House Report states that

> [a]lthough he standard for defining the regulatory authority of the Administrator throughout the bill is "unreasonable risk," the implementation of the standard will of necessity vary depending on the specific regulatory authority which the Administrator seeks to exercise. For example, a testing rule under Section 4 will ordinarily not result in depriving the public of the benefits of a substance or mixture subject to the rule. This is because such a rule doe not prohibit the manufacture, processing, etc., of existing substances or of mixtures . . .
>
> However, this is to be contrasted with the effect of the imposition of a requirement under Section 6 on a substance. Such a requirement may remove a substance from

> the market or impose lesser restrictions on its availability and such a requirement is not of limited duration. Thus, the effect on society may be far reaching. As a result . . . because the regulatory effect of action taken under [Section 4] . . . is less than that of action taken under Section 6, the requirements for a determination of unreasonable risk for purposes of Section 4 . . . are less demanding. [Legislative History, pp. 422-3]

ACTION UNDER SECTION 4(f)

If EPA receives test data submitted under TSCA or any other information that indicates "that there may be a reasonable basis to conclude that a chemical substance or mixture presents or will present a significant risk of serious or widespread harm to human[s] . . . from cancer, gene mutations, or birth defects," EPA must initiate appropriate action under Sections 5, 6, or 7 or publish a finding that the risk is not unreasonable.

The kind of harm sought to be avoided: The harm involved in this situation is "a significant risk of serious or widespread harm to human beings from cancer, gene mutations, or birth defects. . . ." This is a more narrowly defined risk than that comprehended by the term "unreasonable risk." The type of injury is limited to cancer, gene mutations, and birth defects; the potential injury must be serious or widespread; and the risk must be "significant."

The level of causality that must exist between the chemical substance and mixture and the significant risk of serious or widespread harm from cancer, gene mutations, or birth defects: EPA action must be taken if the chemical "presents or will present" the harm to be avoided. The causal connection must, therefore, be more certain than under Section 4(a) where "may present" was sufficient causality to trigger EPA action.

The criteria or factors to be considered: EPA must have a "reasonable basis to conclude" that the requisite harm, causality, and risk exist. Further, EPA's action must be such as to reduce to a "sufficient extent" the risks involved. EPA does not have to act if it determines that the risk involved is not "unreasonable."

ACTION UNDER SECTION 5(b)(4)(A)

EPA may, by rule, compile and update a list of certain chemical substances for which EPA finds the manufacture, processing, distribution in commerce, use, disposal, or combination of these activities "presents or may present" an unreasonable risk of injury to health or the environment (5(b)(4)(A)). If a chemical substance is on this list and no Section 4 testing rule has been promulgated for it before a premanufacturing notice[6] regarding it is submitted, the submitter must provide EPA with data that shows that the chemical substance does not present an unreasonable risk of injury.

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[6] Section 5(a) requires a person planning to manufacture a new chemical or planning to manufacture or process a chemical for a significant new use to provide EPA with a notice containing certain information.

The kind of harm sought to be avoided: The harm involved in this situation is the frequently used and previously discussed "unreasonable risk of injury to health or the environment."

The level of causality that must exist between activities with the chemical substance and the unreasonable risk of injury: EPA may add the chemical substance to the list if activity with the chemical "presents or may present" the harm to be avoided. The causal connection between the activity and the harm, therefore, need not be relatively certain.

The criteria or factors to be considered: Any such finding by EPA that supports its action to compile a list must include all "relevant factors" including "the effects of the chemical substance on health [and the environment] and the magnitude of human [and environmental] exposures" to the chemical substance. (Section 5(b)(4)(A)(ii))

ACTION UNDER SECTION 5(e)

If EPA lacks the information necessary to make a reasoned evaluation of the health and environmental effects of a chemical substance for which a premanufacturing notice is required to be submitted, there are two instances in which EPA may, by proposed order, limit or prohibit the manufacture, distribution in commerce, processing, use, or disposal of such a chemical.[7J] The two instances are:

[7J] There are limits to EPA's authority to issue such a proposed order. One commentator notes:

[T]he rules for imposition of an immediate restriction on a chemical [are] change[d] if EPA acts after 45 days prior to expiration of the [premanufacturing] notice period. Section 5(e)(1)(B). At that point, the substantive criteria for action become stricter.

If the agency wants to act when there are 45 or fewer days left in the premanufacturing notice period, two criteria must be met for EPA to prohibit manufacture, processing, or distribution of a chemical: (1) EPA must declare a proposed rule (imposing these sanctions) to be effective upon publication in the Federal Register, and (2) a court must have found that the chemical subject to this rule poses "an imminent and unreasonable risk of serious or widespread injury to health or the environment." Sections 6(d)(2)(A)(ii), 7(a),(f). If the sanctions EPA seeks to impose are less severe than a prohibition, the agency still must find that there is "an unreasonable risk of serious or widespread injury to health or the environment." Section 6(d)(2)(A)(i). If EPA acts before the 45 day period begins, it need not find that the potential injury is imminent, widespread, or serious--it merely must find that the risk of injury is unreasonable, or that the chemical will be produced in substantial quantities or that human or environmental exposure will be substantial. (See the text following this note). Zener, "The Toxic Substances Control Act," 32 The Business Lawyer 1685, 1695 (1977).

- The lack of necessary information leaves open the possibility that these activities may present an unreasonable risk of injury to health or the environment.

- The production quantities of the chemical substance are or will be substantial, the chemical is or can reasonably be expected to enter the environment in substantial quantities, and human exposure to it is or may be significant or substantial.

This authority differs from Section 4(a) which applies to all chemicals. Under Section 5(e), only new chemicals or existing chemicals which are being considered for a significant new use are covered. It might be thought that Section 4(a) could cover these, too, but Section 4(a) is limited to (1) chemicals about which enough is known to cause some concern and to indicate that more information is needed (see Legislative History, p. 424), and (2) chemicals produced in large quantities. New chemicals or chemicals for significant new uses, the subject of Section 5(e), may fit neither of these categories.

The kind of harm sought to be avoided: This situation is very similar to Section 4(a). The same harm is involved--"an unreasonable risk of injury."

The level of causality that must exist between a chemical substance and the unreasonable risk of injury or the substantial exposure: The required level of causality is, as with most situations under TSCA, fairly low. The chemical substance is subject to EPA action if it "may present" an unreasonable risk, if the exposure of the environment occurs or "may reasonably be anticipated" to occur, and if significant or substantial human exposure occurs or "may" occur.

The criteria or factors to be considered: The action must be based on a determination by EPA that:

(1) there is insufficient information to make a "reasonable evaluation" of the chemical substance's effect on health and the environment, and

(2) without being able to make the necessary evaluation, the harm sought to be avoided "may" occur.

This two-part test indicates that agency action is justified if there is going to be a certain level of human and environmental exposure without enough information to determine whether any potential harm may come from the exposure.

ACTION UNDER SECTION 5(f)

If EPA finds that there *is* an unreasonable risk of injury involved in the manufacture, processing, distribution in commerce, use, or disposal of a new chemical substance or a chemical substance for a significant new use, and if it finds that this risk occurs before a Section 6 rule can provide protection, then EPA must take one of two actions:

- issue a proposed rule under Section 6(a) (related to the regulation of hazardous chemicals and substances) that may limit (but not prohibit) activity related to the chemical substance and which will be effective upon its publication in the Federal Register; or
- issue a proposed order to prohibit the manufacture, processing, or distribution of the chemical substance.[13]

The kind of harm sought to be avoided: EPA is to act to avert an "unreasonable risk of injury to health or environment." This is the harm with which TSCA is most frequently concerned, and it has been discussed previously.

The level of causality that must exist between activities with the chemical substance and the unreasonable risk of injury: The activity related to the chemical substance will be limited or prohibited if it "presents or will present" an unreasonable risk of injury. The causal link must be more certain than when the criterion is "may present." This is in keeping with the Congressional intent to require a stronger causal link between the chemical and the harm where the action EPA can take is more severe.

The criteria or factors to be considered: EPA must have a "reasonable basis" for concluding that an "unreasonable risk of injury" is involved. In addition, the harm must be fairly imminent--occurring before a Section 6 rule could rectify the situation. Although the term "imminent" is not used in the section, the conference report indicates that that is the situation contemplated by this section. (See Legislative History, p. 683)

Although a similar authority to make a proposed rule effective upon publication exists under Section 6(d), Section 5(f) differs in that it requires only an "imminent, unreasonable risk of injury, regardless of whether the injury will be serious or widespread," (Legislative History, id.) and involves only new chemicals or chemicals to be put to a significant new use. Under Section 6(d) the injury must be serious or widespread, but Section 6(d) is applicable to all chemicals.

ACTION UNDER SECTION 6(a)

EPA is required, by rule, to place a variety of restrictions on the manufacture, processing, distribution, use, or disposal of a chemical substance or mixture, or any combination of these activities, whenever it has a reasonable basis for concluding that any of these activities presents or will present an unreasonable risk of injury to health or the environment. The restrictions include prohibitions or limitations on these activities, markings and warnings to be placed on the chemical substance or mixture, various levels of recordkeeping, and some notification requirements.

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[13] EPA's authority to issue a prohibitory order is limited by the 45 day period discussed in footnote 4.

The kind of harm sought to be avoided: Again, the harm to be protected against is "an unreasonable risk of injury to health or the environment." The meaning of this phrase has been discussed previously. The Section 6 title refers to the substances subject to regulation as "hazardous chemical substances or mixtures."

The level of causality that must exist between activities and the unreasonable risk: The causation requirement is "presents or will present an unreasonable risk." The meaning of this phrase also has been previously discussed.

The criteria or factors to be considered: EPA must have a "reasonable basis" for concluding that an unreasonable risk exists. In deciding which regulatory restriction to impose, EPA must select the restriction that both protects "adequately" against the risk and imposes "the least burdensome requirements." These general directives are supplemented by a list of explicit considerations (6(c)(1)) that EPA must make and publish in promulgating a Section 6 rule:

- the effects the chemical substance or mixture has on health and the environment and the magnitude of human and environmental exposure to the chemical substance or mixture;
- the "benefits" the chemical substance or mixture has for "various uses," and the availability of substitutes for their uses; and
- "the reasonably ascertainable economic consequences of" the Section 6(a) rule, taking into consideration its effect on "the national economy, small businesses, technological innovation, the environment, and public health."

Further, if EPA determines that the risk involved is "eliminated" or sufficiently reduced by other legislation administered wholly or in part by EPA, EPA may not promulgate a Section 6(a) rule unless it finds, in its discretion, that the public interest requires application of TSCA to prevent the risk (6(c)(1)). In making this finding, EPA must consider (but evidently need not publish):

- "all relevant aspects of the risk," as determined by EPA in EPA's discretion;
- comparison of estimated compliance costs under TSCA and under the other relevant statutes; and

- the "relative efficiency" of actions under TSCA versus under the other relevant statutes.

The statement EPA is required to publish is not to be a formal, detailed report. The conference report indicated that a "succinct and precise statement of these key considerations will suffice." The cost to the industry is to be considered; the Senate Report suggests that "it is expected that the chemical industry will come forward with data bearing on the actual costs of compliance." (Legislative History, p. 176) Presumably, industry recalcitrance in providing such information would limit industry's ability to attack successfully EPA's consideration of relative compliance costs.

ACTION UNDER SECTION 6(b)

EPA, by order, may require a manufacturer or processor of a chemical substance or mixture to submit a description of its quality control procedures, if EPA has reasonably concluded that the manufacture or processing of the chemical is done in a manner that unintentionally causes the chemical to present or will cause it to present an unreasonable risk of injury to health or the environment. After reviewing these procedures, EPA may order their revision, and may require the manufacturer or processor to give notice to processors, distributors, exposed individuals, and the public regarding the risk associated with the chemical substance or mixture, and to provide any replacement or repurchase necessary.

The kind of harm sought to be avoided: The harm to be avoided is "unreasonable risk of injury to health or the environment," a concept previously discussed.

The level of causality that must exist between the manufacture or processing of the chemical and the unreasonable risk: EPA may take this regulatory action in the face of a manufacturing or processing procedure "which unintentionally causes the chemical substance or mixture to present or which will cause it to present an unreasonable risk of injury to health or the environment. . . ." (emphasis added) The causal link must be strong. The manner of manufacture or processing must actually cause the risk of injury to be presented. It is not sufficient that the production practices in question "may" cause the risk.

The criteria or factors to be considered: EPA must have a "reasonable basis" for concluding that the harm is being caused by the manner in which the chemical substance is being manufactured or processed. In addition, the determination by EPA that the quality control procedures in question are inadequate must be made on the record following a hearing that has been held in accordance with the Administrative Procedures Act.

ACTION UNDER SECTION 6(d)(2)

If EPA determines that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture subject to a proposed 6(a) rule, is likely to result in an unreasonable risk of serious or widespread injury before the 6(a) rule is final, and if the public interest requires it, EPA may make the proposed 6(a) rule effective immediately upon its publication in the Federal Register.[9]

The kind of harm sought to be avoided: The harm protected against is "an unreasonable risk of serious or widespread injury to health or the environment." Note that this harm criterion is more restrictive than the usual "unreasonable risk of injury to health or the environment." Instead of any injury, it must be "serious or widespread."

The level of causality: The level of causation is that the manufacture, distribution in commerce, processing, use, or disposal of a chemical substance or mixture, or any combination of these activities, "is likely to result" in the harm mentioned. This level of causation is more rigorous than the normal "will or may present an unreasonable risk." Instead, EPA may take this action only if the activities are "likely to result" (unfortunately, the legislative history provides no interpretation of this term) in the unreasonable risk of the widespread or serious injury.

The criteria or factors to be considered: The harm must be "likely to result" before the date when the proposed rule would become final, and EPA must determine that the early effective date is "necessary to protect the public interest." In addition, if the proposed Section 6(a) rule would prohibit the manufacture, processing, or distribution of a chemical substance or mixture because of the unreasonable risk of serious or widespread injury, a court must already have granted relief (including a court order that the manufacturer, processor, or distributor provide notice of the risk to purchasers and the public, issue a recall, or replace or repurchase the chemical involved) under Section 7 of TSCA regarding this unreasonable risk before EPA can make the proposed rule immediately effective. The reason for this requirement is noted in the House Report:

> It is because of the severity of a rule which prohibits the manufacture, processing, or distribution in commerce of a substance or mixture, that the Committee required an action be brought under section 7 (imminent hazard) to have a federal district court find that the substance or mixture is an imminent hazard. [The action need not be brought against all persons involved in manufacturing, processing or distributing the chemical.] . . . Once a court finds an imminent hazard in the action under Section 7, a banning rule of general applicability may then be made immediately effective with respect to all others. [Legislative History, p. 446]

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[9] Failure to take this action authorized by Section 6(d)(2)(A)(i) obligates EPA to bring the civil suit authorized in Section 7(a). See the discussion of Section 7(a), below.

ACTION UNDER SECTION 6(e)

EPA is given broad regulatory authority over polychlorinated biphenyls (PCBs). EPA must regulate the disposal of PCBs and must require warnings and instructions to accompany PCBs. In addition, EPA may exempt some activity with PCBs from statutory prohibitions (6(e)(2)(B)), and authorize some use of PCBs other than in a totally-enclosed manner (6(e)(3)(B).

The kind of harm sought to be avoided: The well-documented hazards posed by PCBs were the impetus for this section. Exemptions from statutory prohibitions and authorizations for non-totally-enclosed uses are based, in part, on an avoidance of "an unreasonable risk of injury to health or the environment."

Certainty/causality criteria: EPA may grant (3)(B) exemptions or authorize (2)(B) uses if EPA finds that an unreasonable risk of injury to health or the environment "would not result" and "will [not be] present," respectively. These are criteria for which there is little tolerance for uncertainty.

Factors to be considered: Apart from the criteria listed above, Section 6(e) contains no factors for consideration in establishing PCB rules under TSCA. To implement the authority, EPA employed the factors listed in Section 6(c)(1) for making the required unreasonable risk findings under Section 6(e). (See review of these factors in Section 6(a) regulatory authority, above.) The Circuit Court of Appeals for the District of Columbia declared this to be "entirely appropriate" and held that EPA properly applied these factors.[10] To exempt "totally enclosed" uses, furthermore, EPA must, by rule, determine that "any exposure of human beings or the environment to a polychorinated biphenyl will be insignificant." (6(e)(2)(C)). The Court is given free rein to place any terms and conditions on such an exemption.

ACTION UNDER SECTION 7(a)

EPA is given authority to bring a civil suit to seize an imminently hazardous chemical substance or mixture or any article containing such a substance or mixture and/or obtain appropriate relief[11] against persons manufacturing, distributing in commerce, processing, using, or disposing such a substance, mixture, or article. EPA must take this action if it has not made a proposed section 6(a) rule immediately effective when an imminently hazardous chemical substance or mixture is involved.

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[10] EDF v. EPA, 15 ERC 1081, 1088 (D.C. Cir. 1980).

[11] Such other relief includes a requirement that notification of the risks involved be given to purchasers of the imminently hazardous chemical, that there be public notice of such risk, that the chemical be recalled, that the chemical be replaced or repurchased, some combination of these remedies, or that the chemical be seized or condemned. (7(b)(2) and (3))

The kind of harm sought to be avoided: The harm to be protected against is an "imminent and unreasonable risk of serious or widespread injury to health or the environment." The Conference Report notes that the physical manifestations of the injury need not be imminent, and that "widespread" can mean "risk of harm affecting a substantial number of people, even though" they are within a limited geographic area. (Legislative History, p. 691)

The level of causality that must exist between activities involving the chemical and the imminent hazard posed by the chemical: The level of causality required is that the imminent hazard must be "presented" by the chemical substance or mixture in question. Imminence is considered to be present if the activities related to the chemical substance or mixture are "likely to result" in the harm before a final Section 6 rule can protect against the risk. The House Report notes that "[s]uch protection would not necessarily occur upon the effective date of a rule under Section 6. Instead, consideration must be given to the time it may take to implement and enforce such a rule." (Legislative History, pp. 447-448)

The criteria or factors to be considered: A federal district court must determine that the manufacture, processing, distribution, use, or disposal of such a chemical substance or mixture "is likely to result in an unreasonable risk of widespread or serious injury before a final rule under section 6 can protect against such risk."

ACTION UNDER SECTION 8(c)

EPA is to define by rule what is a "significant adverse reaction" for which records must be maintained by a person who manufactures, processes, or distributes in commerce a chemical substance or mixture.

The kind of harm sought to be avoided: The records must be kept for significant adverse reactions.

The level of causality that must exist between the substance or mixture and the adverse reaction: Records must be kept for significant adverse reactions "alleged to have been caused" by a chemical substance or mixture. This is a fairly loose causal requirement. However, in keeping with the rationale behind the Act, the impact on the manufacturer, processor, or distributor is fairly small, so the loose causal requirement is justified.

The criteria or factors to be considered: In determining what is a "significant adverse reaction," the Conference Report indicated that EPA should consider the "seriousness, duration, and the frequency" of the reactions. The Report supplied an example:

> [I]f an individual reports that a chemical substance causes his or her eyes to become inflamed and to tear, such reaction may be attributed to an isolated allergic reaction. However, if several persons report a similar reaction, then the reaction may indeed be significant. Because the ultimate significance of adverse reactions is

> difficult to predict, the conferees intend that the requirement to retain records err on the side of safety. Some very serious neurological disorders, for instance, at first, present what appear to be trifling symptoms." [Legislative History, p. 694]

ACTION UNDER SECTION 8(e)

A person who manufactures, processes, or distributes a chemical substance or mixture in commerce is required to report to EPA information about whether the chemical presents a substantial risk of injury.

The kind of harm sought to be avoided: The harm involved is "a substantial risk of injury to health or the environment." The language of risk is similar to that found in Section 4(f) (discussed above). There the risk was described as "significant," and seems to relate to probability of harm. In addition, the sanction or burden imposed under Section 4(f) (i.e., appropriate action under Sections 5, 6, or 7--including prohibitions on the manufacture of chemicals) is more severe than the burden imposed by Section 8(e) (reports to EPA). As noted earlier, when the burden imposed on persons by TSCA is not great, EPA is not held to as strict a standard of showing that the harm should be the subject of regulatory action. (See Legislative History, p. 422) Thus, EPA is probably not required to find a high probability of injury in determining that a "substantial" risk exists. The Senate committee registered its concern that the Kepone situation--where an employee complaint to the Labor Department was not given proper attention--not be repeated. Section 8(e) is designed to avoid a recurrence of the Kepone-type situation.

The level of causality required to exist between the chemical and the risk of harm: As with much of TSCA, the requirements of the section are triggered if the chemical "presents" the risk of harm.

The criteria or factors to be considered: The information (about the existence of a substantial risk) received by the manufacturer, processor, or distributor must "reasonably" support the conclusion that there is the necessary "substantial risk of injury." The person does not have to report the information if he/she has "actual knowledge" that EPA has been adequately informed of the relevant facts.

TOXIC SUBSTANCES CONTROL ACT -- REGULATORY REVIEW

INTRODUCTION

This section summarizes the designation of chemicals under Sections 4, 5, and 6 of the Toxic Substances Control Act (TSCA). We begin with some brief background on the regulatory process of designating chemicals, and then turn to a discussion of the criteria used in designation and the list of chemicals subject to regulation under each section.

SECTION 4 REGULATIONS

Section 4 of TSCA provides EPA with the regulatory authority to require health and environmental testing of a chemical substance or mixture. TSCA specifies that testing may only be required if insufficient data exist to "reasonably" determine or predict the effects of a chemical on health or the environment, and if testing is necessary to develop the needed data. There are two situations under which EPA may require testing:

(1) If "the manufacture, distribution in commerce, processing, use, or disposal of a chemical substance or mixture, or . . . any combination of such activities, may present an unreasonable risk of injury to health or the environment" (Section 4(a)(1)(A)), or

(2) "A chemical substance or mixture is or will be produced in substantial quantities, and (I) it enters or may reasonably be anticipated to enter the environment in substantial quantities or (II) there is or may be significant or substantial human exposure to such substance or mixture" (Section 4(a)(1)(B)).[12]

TSCA provides a number of mechanisms whereby testing rules may be promulgated, including EPA's own initiative, or a favorable EPA response to a citizens' petition for testing. The most important mechanism at present is the TSCA-mandated interagency advisory committee. Section 4(e) establishes this committee, consisting of representatives of eight agencies, who must develop and submit to EPA a list of chemicals recommended for consideration by the Agency. The first priority list was to be published within nine months of the effective date of TSCA and was required to be revised (if considered necessary) every six months thereafter.

Although EPA reserves the right to consider other chemicals not appearing on the priority list for testing, the Agency has to give priority consideration to the committee's list. Within 12 months of a chemical first being included on the priority list (and targeted by the committee for regulatory action within 12 months), EPA must either initiate a rulemaking proceeding for testing the chemical or publish its reason for not doing so.

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[12] Toxic Substances Control Act, PL 94-469, Oct. 11, 1976, Section 4(a) (Emphasis added). See detailed discussion above, pp. 1-1 through 1-21.

By January 1, 1981, the committee (known as the TSCA Interagency Testing Committee (ITC)) had included 42 entries on the priority list. (TSCA specifies that no more than 50 entries are permitted at any one time.) Because the ITC also included classes of chemicals as single entries on the list, the actual number of chemicals recommended to EPA expands to over a thousand. Of these, EPA has taken action[13] on one class of chemicals (chlorinated benzenes) and two chemical substances (chloromethane and acrylamide). Exhibit 1-2 shows the list of chemicals recommended by the ITC and the dates designated for regulatory action.

Criteria for Designation

In order to discuss the rationale behind the designation of chemicals for testing under TSCA Section 4, it is useful to examine the work of the Interagency Testing Committee which recommends the chemicals to be considered by EPA, before looking at the decisions taken by EPA on those chemicals.

ITC Criteria: TSCA instructs the ITC to consider "all relevant factors"[14] when making recommendations on chemicals, including:

(i) the quantities in which the substance or mixture is or will be manufactured,

(ii) the quantities in which the substance or mixture enters or will enter the environment,

(iii) the number of individuals who are or will be exposed to the substance or mixture in their places of employment and the duration of such exposure,

(iv) the extent to which human beings are or will be exposed to the substance or mixture,

(v) the extent to which the substance or mixture is closely related to a chemical substance or mixture which is known to present an unreasonable risk of injury to health or the environment.

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[13] 45 FR 48524, July 18, 1980; 45 FR 48668, July 21, 1980.

[14] TSCA, Section 4(e)(1)(A).

EXHIBIT 1-2

TSCA Section 4(e) Priority List

Entry:	Designated for EPA Action by:
Acetonitrile	April 1980
Acrylamide	April 1979
Alkytin Compounds	October 1981
Alkyl epoxides	October 1978
Alkyl phthalates	October 1978
Aniline and bromo, chloro, and/or nitroanilines	April 1980
Antimony (metal)	April 1980
Antimony sulfide	April 1980
Antimony trioxide	April 1980
Aryl phosphates	April 1979
Benzidine-based Dyes	November 1980
Benzyl butyl pthalate	October 1981
Butyl glycotyl butyl pthalate	October 1981
Chlorinated benzenes, mono-and di-	October 1978
Chlorinated benzenes, tri-, tetra-and penta-	October 1979
Chlorinated naphthalenes	April 1979
Chlorinated paraffins	October 1978
Cresols	October 1978
o-Dianisidine-based Dyes	November 1980
Dichloromethane	April 1979
1,2-Dichloropropane	October 1979
Cyclohexanone	April 1980
Fluroalkenes	October 1981
Glycidol and its derivatives	October 1979
Halogenated alkyl epoxides	April 1979
Hexachloro-1, 3-butadiene	October 1978
Hexachlorocyclopentadiene	April 1980
Hydroquinone	November 1980
Isophorone	April 1980
Mesityl oxide	April 1980
4,4'-Methylenedianiline	April 1980
Methyl ethyl ketone	April 1980
Methyl isobutyl ketone	April 1980
Nitrobenzene	October 1978
o-Tolidine-based Dyes	November 1980
Phenylenediamines	April 1981
Polychlorinated terphenyls	April 1979
Pyridine	April 1979
Quinone	November 1980
Toluene	October 1978
1,1,1-Trichloroethane	April 1979
Xylenes	October 1978

Source: Seventh Report of the Interagency Testing Committee to the Administrator, Environmental Protection Agency, 45 FR 78432 (November 25, 1980).

(vi) the existence of data concerning the effects of the substance or mixture on health or the environment,

(vii) the extent to which testing of the substance or mixture may result in the development of data upon which the effects of the substance or mixture on health or the environment can reasonably be determined or predicted, and

(viii) the reasonably foreseeable availability of facilities and personnel for performing testing on the substance or mixture.

TSCA also instructs the committee to give priority attention to chemicals which are known or suspected of causing or contributing to cancer, gene mutations, or birth defects.

In each of its seven reports through 1980[15] the ITC has presented its reasons for recommending a chemical or class of chemicals for testing. The committee considered each chemical for six types of testing: carcinogenicity, mutagenicity, teratogenicity, other chronic effects, environmental effects, and epidemiology. Reasons for recommendations typically involve a high production volume for the chemical, a high release rate into the environment, widespread human exposure in the workplace and/or from consumer products, biological activity or known acute toxic effects of the chemical, inconclusive but suggestive previous test results, inability to extrapolate adequately from previous tests, lack of any prior testing, or structural similarity to chemicals known or suspected to be harmful.

EPA Criteria: EPA is instructed by TSCA that the "health and environmental effects for which standards for the development of test data may be prescribed include carcinogenesis, mutagenesis, teratogenesis, behavioral disorders, cumulative or synergistic effects, and any other effect which may present an unreasonable risk of injury. The characteristics of chemical substances and mixtures for which standards may be prescribed include persistence, acute toxicity, subacute toxicity, chronic toxicity, and any other characteristic which may present such a risk."[16]

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[15] These were published as follows:

First report: 42 FR 55026, October 12, 1977 Second report: 43 FR 166874, April 19, 1978 Third report: 43 FR 50630, October 30, 1978. Fourth Report: 44 FR 31886, June 1,1979. Fifth Report: 44 FR 70664, December 7,1979. Sixth Report: 45 FR 35897, May 28,1980. Seventh Report: 45 FR 78432, November 25, 1980.

[16] Section 4(b)(2)(A) continues: "The methodologies that may be prescribed in such standards include epidemiologic studies, serial or hierarchical tests, in vitro tests, and whole animal tests. . . ."

As of this report, EPA has not issued any final standards for testing under Section 4. However, in its first proposed rule[17] requiring testing under Section 4, EPA outlined its approach to determining the need for a testing rule. EPA differentiates between the evidence necessary to make a risk-based finding (Section 4(a)(1)(A)) and an exposure-based finding (Section 4(a)(1)(B)). The agency notes that the former finding ("may present an unreasonable risk") is relevant where there is a scientific basis for suspecting potential toxicity and where the potential for risk may be significant even when the potential for exposure seems small. There is a need to show exposure in order to make a Section 4(a)(1)(A) finding, however, the exposure threshold is much lower than under Section 4(a)(1)(B). In the latter case, EPA can require testing, "not because of suspicions about the chemical's safety, but because there may be substantial or significant human exposure to a chemical whose hazards have not been explored."[18]

EPA stated the following policy for purposes of Section 4(a)(1)(A):[19]

> If there is substantial evidence that exposure to a chemical may lead to a serious health effect or increase in mortality and that people may be exposed to the chemical, EPA will presume that the activities in question (manufacturing, processing, using, transporting, disposing) "may present an unreasonable risk" unless the rule is likely to result in a significant loss to society of the benefits of the substance. In the latter instances, if EPA's analysis shows that the costs of testing may cause manufacturers or processors to cease or severely restrict their commercial activities, EPA will weigh this potential adverse impact against the benefits of testing before presuming that the chemical may present an unreasonable risk. Whether this balancing is necessary will depend upon the economic impact of each rule.

In this same proposed rule, EPA outlined the steps it takes as general policy in making a finding of insufficiency of data. Most of the agency's efforts are directed at a detailed and critical literature review. Because the ITC listed all recommended chemicals as being of equal priority, EPA is proceeding with its review and rulemaking more or less in chronological order of the date of recommendation by the ITC.

It is worth noting that EPA's proposed rules differ from the ITC's recommendations in a number of ways. This is shown in Exhibit 1-3 which presents EPA's proposed test rules for seven chemicals and final decision on an eighth, and compares the tests and reasons for testing with the ITC recommendations. The difference between the ITC recommendations and EPA's rulemaking is expected because the two organizations are working under different ground rules. Thus, the ITC may recommend a chemical for testing even if it is aware of test studies already going on. EPA, on the other hand, may decide not to require testing because of tests that have been initiated. (This is the case for acrylamide, where EPA decided not to require oncogenicity testing in part because Dow Chemical Company planned to test the substance.)

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[17] Chloromethane and Chlorinated Benzenes Proposed Test Rule, 45 FR 48524, July 18, 1980. At this time, EPA also issued the decision not to order testing for acrylamide, another substance on the ITC list.

[18] Preamble to Proposed Rule, p. 48528.

[19] Ibid, p. 48529.

Secondly, EPA may defer test requirements recommended by the ITC if appropriate test standards or complete test sequences have not been developed. (For example, EPA deferred mutagenicity testing for chloromethane in its proposed rules.)

Third, EPA may come to different conclusions from its intensive review of the literature than the recommendations reached by the ITC. This is expected by both parties because (a) the ITC works within an even tighter deadline than the Agency and may not have available all the data eventually gathered by EPA; and (b) EPA must consider the appropriate allocation of its own regulatory activities and of the cost burden of testing chemicals. For example, EPA decided that acrylamide should not be tested because enough is known about its neurotoxicity to move towards adopting regulatory controls. Because controls adopted for the chemical's neurotoxicity would likely protect against its other effects, EPA decided not to require a complete assessment of these nonneurological effects, stating that the Agency's "rulemaking activities should be devoted to more pressing testing needs concerning chemicals about which much less is known."[20]

Fourth, the issue of using categories of chemicals is dealt with differently by EPA and the ITC. Under Section 26(c) of TSCA, EPA is permitted to use categories of chemicals in rulemaking in the same manner as individual chemicals (as long as the classification is suitable for purposes of the Act).[21] As noted, the ITC made use of this provision in designating a large number of chemical categories for inclusion on the priority list. EPA, however, must not only review all available data on each member of a recommended category, but decide whether and how to sample the category for testing purposes to meet both validity requirements and the needs of the reimbursement system.

In the case of chlorinated benzenes, EPA selected six members of the category for testing out of a total of 11. (Hexachlorobenzene is a member of the chlorinated benzenes family but was not included in the ITC's recommendations. It is being regulated by EPA under RCRA.) EPA chose the sample in order to "represent all levels of chlorination, the full range of physio-

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[20] EPA Response to the Interagency Testing Committee and Decision Not to Propose Further Testing of Acrylamide, 45 FR 48668, July 21, 1980.

[21] TSCA describes a category as "a group of chemical substances the members of which are similar in molecular structure, in physical, chemical, or biological properties, in use, or in mode of entrance into the human body or into the environment . . ."(Section 26(c)(2)(A)).

EXHIBIT 1-3 GOES HERE

EXHIBIT 1-3

TESTING REQUIRED UNDER SECTION 4

Chemicals	ITC Recommendation	EPA Proposed Rule and Reasons	
1. Chloromethane	Carcinogenicity Teratogenicity	• Oncogenicity • Structural Teratogenicity	Chloromethane has potential to cause these effects; considerable number of workers exposed.
	Mutagenicity	• No testing for Behavioral Teratogenicity, Neurotoxicity, or or Mutagenicity because EPA is not prepared to specify appropriate test standards at this time. However, EPA plans to arrange for performance of most of the mutagenicity tests in the interests of public health.	
	Other chronic effects	• No testing	No effects have been found in tests, therefore no further testing needed.
		• No testing for reproductive effects, acute toxicity, metabolism (not necessary), or epidemiology (cohort not identified yet)	
2. Chlorinated Benzenes (Representative Sample Monochlorobenzene ortho-Dichlorobenzene para-Dichlorobenzene 1,2,4-trichlorobenzene 1,2,4,5-tetrachlorobenzene Pentachlorobenzene)	Carcinogenicity	• Oncogenicity (for tri-, tetra-, penta-)	Show oncogenic potential. Others are being tested already by NCI.
	Teratogenicity	• Structural Teratogenicity • Reproductive Effects	Potential for these effects has been shown; most have not been tested.
	Other chronic effects	• Subchronic/Chronic Effects	Associated with damage to liver, kidney and hematopoietic system. Available data insufficient to determine appropriate level of exposure control.
	Epidemiology	• No testing	EPA unable to identify suitable cohort.
	Mutagenicity	• Testing deferred However EPA plans to arrange for most of mutagenicity tests to be performed.	Test sequence has not been specified.
		• Testing deferred for Behavioral Teratogenicity, Neurotoxicity, or Metabolism--appropriate test standards unavailable. • No testing for acute toxicity--data already available.	
	Environmental effects	• Deferred	Standards for environmental effects testing unavailable.
3. Acrylamide (final decision)	Carcinogenicity Mutagenicity Teratogenicity Epidemiology	• No testing	Neurotoxicity well documented, oncogenicity study to be done by Dow Chemical Company. Enough data available to evaluate acrylamide for regulatory control.
	Environmental Effects	• Testing deferred	Evaluation of hazard incomplete, standards unavailable.

chemical properties, and compounds having the highest commercial production among the chlorinated benzenes." The Agency was able to choose this sample, in part, because "the structural relationships among the chlorinated benzenes lead to the expectation of regular progressive changes in properties going through the series." EPA found "a reasonable presumption that the biological behavior of these 11 chemicals will present a coherent picture of toxicity and that biological data on a well-chosen sample of category members can be used to characterize the biological behavior of the untested members."[22]

Finally, EPA must write test rules that are well-specified and justifiable as regulations. Thus, for example, EPA agreed with the ITC that an epidemiological study of chloromethane would be useful, but was unable to propose requiring one because of the lack of information needed in order to identify a suitable cohort.

In the preamble to its first proposed test rules, EPA acknowledges this uncertainty and requests comments on virtually every aspect of the rulemaking. On the technical side,[23] for example, EPA raised questions such as:

- "Should EPA require behavioral teratogenicity testing of chloromethane? If so, what test methodologies for assessing behavioral teratogenic endpoints are appropriate for chloromethane?"

- "Will oral subchronic tests on the chlorinated benzenes using only the rat (i.e. only one species) be sufficient to characterize the risk of subchronic/chronic effects?"

Some of the general issues raised in the preamble are worth recording here in some detail, because they go to the heart of the decision-making process under Section 4. For example, comments were solicited on the following questions:[24]

- "How much exposure information is pertinent to the unreasonable risk finding under Section 4(a)(1)(A)(i)?"

  ("EPA has taken the position that as long as it can be shown that some exposure to a substance exists or that there is a potential for such exposure, and there is the potential for serious health effects, a Section 4(a)(1)(A)(i) finding can be made.")

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[22] Preamble to Proposed Test Rules, 45 FR 48554.

[23] pp. 48558-48561.

[24] pp. 48561-48563.

- "Is the Agency's approach to deciding what substance to test the most appropriate one?"

  ("EPA considered a totally ad hoc approach for determining what to test versus a case-by-case approach within a general policy stating considerations for selecting a test substance considered for purposes of Section 4 of TSCA. EPA decided upon the latter course.")

- "What role should information about exposure play in constructing a structure-based category meeting the finding under Section 4(a)(1)(A)(i) of TSCA?"

  (EPA considered whether chemicals in a category which are not commercially produced and which result in little or no exposure should be included in the category for testing purposes. EPA believes that it would be appropriate to consider a chemical as a member of the category if (a) it is commercially produced or a by-product of commercial production or (b) if it is a reasonable substitute for a substance that is commercially produced.)

- "With respect to testing to be required for structure-based categories, should EPA utilize a sampling approach where the sampled members are considered to be representative of all members of the cateogry, or require full testing of all members? If the former approach is chosen, what approach should EPA use in determining what is an appropriate subset to sample?"

Four alternative sampling approaches were considered by EPA as follows:

A. No sampling--test every category member. EPA considers this option infeasible.

B. Sample only when there is strong evidence that one or more substances can, in fact, represent the category. EPA believes this option would almost eliminate the use of categories because it requires information unavailable at the time of rulemaking.

C. Test the highest or most critical exposure chemicals. This option was rejected because the chemicals chosen would not necessarily be representative.of the category.

D. Sample on the basis of spanning the structural spectrum of a category taking into account exposure and production information. This option was chosen in the proposed rules because it permits extrapolation to other category members.

It is doubtless the case that many of these issues were raised in the first proposed testing rules precisely because this was the first opportunity for public comment on an actual Section 4 rulemaking. Nevertheless EPA's policy on some of these issues will likely continue to be uncertain and subject to change in the near future.

Naming Conventions

Chemicals subject to regulation under Section 4 (and those recommended by the ITC) are designated by their generic names and CAS numbers. Categories are usually defined by their molecular structures, and member chemicals are specified.

For example, the definition of the chlorinated benzenes category is "the group of substituted benzene compounds in which one to five hydrogen atoms of benzene are replaced by chlorine atoms, with no substituents present other than chlorine and hydrogen."[25] Category members are listed as:

(i) mononochlorobenzene (chlorobenzene, CAS No. 108-90-7),

(ii) 1,2-dichlorobenzene (ortho-dichlorobenzene, CAS No. 95-50-1), etc.

Test Methods

Because Section 4 regulations require industry to test their chemicals, the issue of test methods is of primary importance. As discussed above, in many cases EPA has been unable to propose test rules because of the unavailability of test standards (such as for environmental effects), the lack of an appropriate test sequence (such as for mutagenicity testing), or an inability to specify an element of the test method (such as the identity of the cohort in an epidemiological study).

EPA has felt a need to specify in its rules precisely which testing protocols are to be followed in order for test results to be considered valid under Section 4. In its proposed health effects test standards under TSCA (44 FR 27334 and 44 FR 44054), the Agency described the proper conduct of each test, including the frequency, duration, and method of dosing (e.g., 1-4 hours single inhalation dose); the required test species, sex, age, and numbers of animals and groups; treatments and observations, and procedures to be followed (e.g. histopathology, hematology). The Agency typically cites references to protocols that have been developed and used in the toxicology literature.

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[25] 40 CFR 773, Subpart B (proposed)(45 FR 48564).

In its first set of proposed rules, EPA specified which tests were to be performed on which chemicals. In certain cases EPA amended the test standards proposed earlier, or specified in more detail some of the test methods. For example, testing of chlorinated benzenes for oncogenicity must be done on a particular (Sprague-Dawley) strain of rats.

Mixtures

TSCA explicitly allows for the testing of mixtures under Section 4(a)(2), if the health or environmental effects of a chemical mixture "may not be reasonably and more efficiently determined or predicted by testing the chemical substances which comprise the mixture." To date, the ITC has not recommended any mixtures for testing.

Section 4(f)

This section of TSCA describes the actions required by EPA upon receipt of any test data submitted under the Act or any other information, "which indicates to the Administrator that there may be a reasonable basis to conclude that a chemical substance or mixture presents or will present a significant risk of serious or widespread harm to human beings from cancer, gene mutations, or birth defects." Within 180 days of receipt of such information, (and a possible extension of an additional 90 days) EPA is required to "initiate appropriate action under Section 5, 6, or 7 [of TSCA] to prevent or reduce to a sufficient extent such risk or publish in the Federal Register a finding that such risk is not unreasonable."

Section 4(f) went into effect on January 1, 1979. As of January 1, 1981, EPA has not determined its final policy on the section.

SECTION 5 REGULATIONS

Section 5 of the Toxic Substances Control Act (TSCA) provides EPA with considerable authority to prevent the manufacture of chemicals that may present an unreasonable risk of injury to health or the environment. This authority is realized, first, by the requirement of premanufacture notification, whereby EPA must be notified before the manufacture of a new chemical substance or of a chemical substance for a significant new use.

Once EPA has received premanufacture notification, the Agency may regulate the chemical under Section 5(e) of TSCA if further information is required to determine the risk presented by the chemical. If EPA finds that the chemical presents an unreasonable risk, the Agency may regulate the chemical under Section 5(f).

The following sections review each of these components of the Section 5 regulatory program.

Premanufacture Notification[26]

EPA proposed regulations on premanufacture notification requirements and review procedures in January 1979,[27] and reproposed revised guidelines in October 1979.[28] Meanwhile, however, the requirement of premanufacture notification is in force, and the chemical industry has been using the forms and guidelines supplied by EPA in the reproposed rules.

Although it is not clear exactly what will be required in the final notification rules, it is likely that the following information will be mandatory for each new chemical:

a. A description of the new chemical substance: chemical identity, molecular structure, Chemical Abstracts Service (CAS) registry number, common or trade name;

b. The estimated total amount to be manufactured and processed;

c. The proposed categories of use;

d. The estimated amount to be manufactured and processed for each category of use;

e. The manner and methods of distribution in commerce (including transportation) and disposal;

f. Descriptions of exposure levels of humans and ecological populations to the chemical substance;

g. All known test data on the health effects, ecological effects, physical and chemical properties, environmental fate characteristics, and exposure of the substance to humans or the environment.

Optional information to be submitted may include descriptions of engineering safeguards and controls; industrial hygiene considerations and other measures to be used to limit exposure; explanations of risk to health and the environment resulting from the manufacture, processing, distribution in commerce, use or disposal of the chemical substance, including explanations of test programs used to assess risk; etc.

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[26] Because the notification requirements encompass both manufacture and imports of new chemicals, and in some cases, processing of chemicals, EPA sometimes uses the broader term "Section 5 notification".

[27] 44 FR 2242, January 10, 1979.

[28] 44 FR 39764, October 16, 1979.

Chemicals Subject to Notification Requirement

As noted above, there are two types of chemicals subject to premanufacture notification. The intention to manufacture new chemical substances must be reported; new chemicals are those which do not appear on EPA's inventory of chemical substances. The inventory, required by Section 8(b) of TSCA, lists all chemicals known to be in production between January 1, 1975 and May 1, 1978; chemicals not included on the inventory are considered "new."

Also subject to notification requirements is the manufacture or processing of a chemical substance for a significant new use. EPA may determine that the use of a chemical is a significant new use after considering the following factors:

(1) the projected volume of manufacturing and processing of the chemical;

(2) the extent to which a use changes the type or form of exposure of human beings or the environment to the chemical;

(3) the extent to which a use increases the magnitude and duration of exposure of humans or the environment to the chemical; and

(4) the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.[29]

The notification requirement for significant new uses is therefore qualitatively different from the requirement for new chemicals. Although TSCA does not mention unreasonable risk with regard to making a determination of significant new use, it is likely that significant new use rules will be developed only for chemicals for which there is some concern about expansion or shifts in uses.

Because EPA has not yet issued any "significant new use rules" (SNURs), it is difficult to say how the Agency intends to use this authority. It is also difficult to classify SNURs as "designation" or "regulation" actions. The only regulation that is inherent in a SNUR is the premanufacture notification requirement. For example, EPA might issue a SNUR for any increased production of a particular chemical above a certain volume. If the manufacturer's notification shows that exposure will not increase appreciably, EPA may decide that no further regulatory actions are needed.

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[29] TSCA, Section 5(a)(2).

Nevertheless, by virtue of the fact that the determination of significant new use will likely rest on concerns about the health effects of the chemical, the SNUR may be considered a preliminary form of designation.[30]
The first SNUR was proposed in November, 1980, for N-methanesulfonyl-p-toluenesulfonamide.[31]

Regulation Pending Development of Information--Section 5(e)

Based on the information submitted in the premanufacture notification, if EPA finds that there is not enough information to make a "reasoned evaluation of the health and environmental effects" of the chemical, and the substance may present an "unreasonable risk" to health and the environment, or will be produced in substantial quantities, or there may be significant or substantial exposure, EPA can issue a proposed order to prohibit or limit the manufacture, processing or distribution of the substance. This is authorized by Section 5(e) of TSCA.

The order (or, in some cases, court injunction) is intended to remain in effect until the manufacturer submits information or test data to EPA that are sufficient to evaluate the health and environmental effects of the chemical.

The findings under Section 5(e) are similar in some respects to the findings EPA makes in issuing testing regulations under Section 4 ("may present an unreasonable risk", insufficient information on chemical effects, "substantial quantities or significant or substantial human exposure"). However, under Section 4, EPA must also make a finding that testing the chemical is required to provide the data needed. Under Section 5(e), EPA has no authority to require testing of the chemical in question.

Of the several hundred premanufacture notifications EPA has received since the inception of the Section 5 program in July 1979, as of January 1, 1981, EPA has taken Section 5(e) action in three instances. In each case, the manufacturer withdrew the premanufacture notification upon being informed of the Section 5(e) action. A brief look at the substances involved in these cases is instructive.

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[30] This is supported by Section 5(g) of TSCA which requires EPA to publish a statement of reasons if the Agency does not initiate action (under Sections 5, 6, or 7) on a significant new use chemical.

[31] 45 FR 78970 (November 26, 1980).

Six Alkyl Phthalate Plasticizers. In May 1980, EPA notified the manufacturer of six alkyl phthalate plasticizers[32] to delay production until the results of further testing were submitted. The basis of this action was the potential carcinogenicity of the plasticizers and their toxicity to aquatic organisms. EPA was alerted to this by data on a related phthalate which has been shown to be a liver carcinogen in animals (di(2 ethylhexyl)phthalate). In addition, EPA was concerned about the large production volume of the chemicals. The Agency estimated that 300-400 workers might be exposed during production of the plasticizers, and 1,000-10,000 might be exposed during the fabrication of products. The manufacturer, whose name was held confidential, had not submitted any test data with the notification, and withdrew the chemical because the tests were too expensive (about $4 million by EPA's estimates) and because the company was afraid that further publicity would reveal its identity.

Lubricant Additive. This product is composed of a group of substituted phenol reaction products with C22-30 alkenes; both its name and the name of the manufacturer were claimed confidential. The product is similar to another chemical which is a known skin irritant. On the basis of this information and its estimate that the product might come in contact with over a million people after distribution, EPA requested that the manufacturer carry out skin sensitization tests and report the information. The proposed tests were estimated to take about two months to perform and cost between $6,000 and $14,000. The manufacturer withdrew the chemical from premanufacture review.[33]

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[32] The six substances were reported as:

(1) Polymer of phthalic anhydride, ethylene glycol, heptanol, and 2-ethylhexanol;

(2) Polymer of phthalic anhydride, 1,2-propylene glycol, 1,4-butanediol, 1-octanol, and 1-decanol;

(3) Polymer of phthalic anhydride, ethylene glycol, heptanol, 1-decanol, and 1-octanol;

(4) Polymer of phthalic anhydride, 1,2-propylene glycol, 1,4-butanediol, and 2-ethylhexanol;

(5) Polymer of phthalic anhydride, 1,3-butylene glycol, 1-octanol, and 1-decanol;

(6) Polymer of phthalic anhydride, 1,3-butylene glycol, 2-ethylhexanol.

(Chemical Regulation Reporter, May 2, 1980, p. 117.)

[33] Chemical Regulation Reporter, October 3, 1980, p. 841.

Phthalate Ester Plasticizer. This compound was proposed for production by Union Camp Corporation and withdrawn from the review process on October 7, 1980 *before* EPA issued a Section 5(e) notice. EPA had indicated to the company that additional tests for carcinogenicity and possibly mutagenicity would be required. Similar to the earlier plasticizers subject to Section 5(e), this product was an analogue to substances with potential carcinogenicity and toxicity.[34]

It is important to recognize that EPA's experience with Section 5(e), as with all aspects of the premanufacture program, is quite recent. EPA had originally intended to develop criteria that would indicate when a chemical should be subjected to detailed review, but the Agency has been unable to complete this task. As the Agency gains more experience with the Section 5 programs and develops general criteria for rulemaking, the direction of EPA's regulations will become clearer.

One example of how Section 5 rulemaking could change is shown by EPA's recent suspension of the review process for two chemicals while the manufacturer and agency negotiated tests and controls for the new chemicals. Voluntary suspension of the review process and subsequent negotiation would be akin to a 4(e) consent action, and could present a useful alternative for both EPA and industry to the costly or protracted Section 5(e) rulemaking.[35]

Finally, a major concern in EPA's review of the premanufacture notifications has been the lack of test data submitted for new chemicals. Although EPA cannot require testing under Section 5, the Agency hopes to induce companies to test their chemicals by issuing guidelines in 1981 for tests that should accompany notifications. The guidelines will be based on the minimum premarketing set of data developed by the Organization for Economic Cooperation and Development.

Protection Against Unreasonable Risks--Section 5(f)

In addition to Section 5(e) regulation of new chemicals pending the development of information, EPA can regulate new chemicals under Section 5(f) of TSCA. If EPA determines that the manufacture, processing, distribution in commerce, use or disposal of the chemical *will present* an unreasonable risk before the Agency can take action under Section 6(a) of TSCA, EPA can prohibit or limit the manufacture or processing of the chemical. EPA's regulatory powers under Section 5(f) are identical to its authority under Section 6(a) of TSCA. For example, the Agency can require warning labels, public notification, limitations or prohibitions on the amount of a chemical produced, on particular uses, or on the concentration of a chemical in a particular use. However, the Section 5(f) provisions allow EPA to regulate a new chemical more quickly (by means of an injunction or an immediately effective proposed rule) than would be possible under Section 6.

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[34] This plasticizer is a polyester of adipic and phthalic anhydride, propanediol-1,2 and alkylene diol and octyl alcohol. (Chemical Regulation Reporter, October 10, 1980, p. 881.)

[35] *Chemical Regulation Reporter*, October 10, 1980, p. 882.

EPA has not yet taken any regulatory actions under Section 5(f) nor published a policy statement on its intended interpretation of the law.

SECTION 6 REGULATIONS

Section 6(a) of TSCA gives EPA the authority to act when it finds that there is "a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use or disposal of a chemical substance or mixture presents or will present an unreasonable risk of injury to health or the environment."

EPA is given a wide range of regulatory controls to use under Section 6(a), including labeling requirements, requirements that manufacturers notify the public of risk, and limitations and prohibitions on particular uses of a chemical or on the concentration of a chemical in a particular use. EPA's regulatory authority extends to all aspects of chemical control: manufacture, processing, distribution in commerce, use, and disposal, as well as quality control procedures in individual manufacturing and processing plants (Section 6(b)).

In making a Section 6 rule, EPA must use the "least burdensome" requirements[36] that will give adequate protection against the risk. In promulgating a rule, EPA is required to publish a statement that addresses the effect of the chemical substance on health and the magnitude of human exposure; the effect on the environment and the magnitude of environmental exposure; the benefits of the substance and the availability of substitutes; and the economic consequences of the rule, (including effects on the national economy, small business, technological innovation, the environment, and public health).

As of January 1, 1981, EPA has completed only two rules under Section 6 and is in the process of developing regulations in two other areas. The Agency has not yet published any regulations or policies that present general criteria for determining "unreasonable risk."

The remainder of this paper discusses EPA's actions on three Section 6 areas: PCBs, chlorofluorocarbons, and asbestos.

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[36] Section 6(a). The term "least burdensome" is not defined in TSCA. However, guidance on the meaning of the term is provided by the list of factors to be considered by EPA when promulgating a Section 6 rule, and by Section 2(b)(3) of TSCA, which states as general policy, that "authority over chemical substances and mixtures should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation. . . ."

Polychlorinated Biphenyls (PCBs)

At the time that TSCA was enacted, the problem of PCB contamination was especially well-publicized. Control of PCBs was written into the Act. EPA was directed to prescribe methods for PCB disposal and to require labeling and instructions on PCB use and handling. Regulations for disposal and marking of PCBs were published in February, 1978.[37] These were integrated into the final rule on the ban of PCBs in May 1979.[38] This rule bans the production of PCB except for specific exemptions which must be approved by EPA. Because the PCB regulations were specifically mandated by Section 6(e) of TSCA, EPA did not have to use the more general authority of Section 6(a), and therefore could pass lightly over the issue of defining unreasonable risk for these regulations.[39]

The final regulations defined all electrical capacitors, electromagnets, and non-railroad transformers as totally enclosed uses, thus automatically exempting them from regulation under Section 6(e). The final regulations also authorized eleven non-totally enclosed uses to continue, based on a consideration of the health and environmental effects of PCBs, the expected exposure, the availability of substitutes for the PCBs, and the economic impact of restricting those uses. The final regulations were reviewed by the U.S. Court of Appeals for the District of Columbia and were, in part, upheld and in part remanded for further proceedings.[40]

The reviewing Court upheld EPA's choice of factors for determining whether non-totally enclosed uses of PCBs will present an unreasonable risk of injury to health or the environment. The factors used are those listed in Section 6(c)(1) which governs the promulgation of rules issued under Section 6(a). These factors are listed above. The Court also approved of EPA's application of these factors.[41]

On the other hand, the Court did not uphold EPA's decision to list several uses of PCBs as "totally enclosed" and therefore exempt from regulation under

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[37] 43 FR 7150, February 17, 1978 (Technical Amendments: 43 FR 33918, Aug. 2, 1978).

[38] 44 FR 31514, May 31, 1979, 40 CFR Part 761.

[39] EPA did make a finding under Section 12(a)(2) of TSCA that the manufacture, processing, and distribution of PCBs for export presents an unreasonable risk of injury to health within the United States. The finding was based on "the well-documented human health and environmental hazard of PCB exposure;" the high probability of human and environmental exposure to PCBs; and the evidence that contamination of the environment by PCBs is spread far beyond the areas where they are used. (40 CFR 761.30)

[40] EDF v. EPA, 15 ERC 1081 (1980).

[41] Ibid., at pp. 1088, 1090.

Section 6(e). The statute defines that expression to mean a use which "will ensure that any exposure of human beings or the environment . . . will be insignificant." The Court held that the record was insufficient to support EPA's findings and classifications.[42]

As part of the regulatory scheme for PCBs under Section 6(e), EPA limited application of the Disposal and Ban Regulations to materials containing concentrations of at least fifty (50) ppm of PCBs, with one exception (i.e., certain uses of waste oil contaminated with any detectable amount of PCBs). The reasons for using a regulatory cutoff included exclusion of ambient sources of PCBs from regulation, exclusion of PCBs created inadvertently during the production process, administrative necessity, and the *de minimis* principle. The reviewing Court held that there was "no substantial evidence in the record to support" a regulatory cutoff of 50 ppm, or any other level, and noted that EPA did not explain why the regulation could not be designed expressly to exclude ambient sources without relying on a regulatory cutoff. The Court emphasized that the authorization and exemption provisions of subsections 6(e)(2)(B) and 6(e)(3)(B) were intended by Congress as means to better tailor PCB control without resorting to a regulatory cutoff. The Court was further troubled that EPA had not determined the amount of non-ambient PCBs excluded from regulation by the 50 ppm or other possible regulatory cutoffs. Additionally, the Court characterized EPA's approach as circumventing the authorization and exemptions provisions of 6(e) and pointed out that EPA had made no finding that the cutoff would involve no unreasonable risk to health or the environment. The Court concluded that EPA needed to conduct further proceedings to justify a regulatory cutoff.[43]

A challenge to EPA's PCB regulations arose over the definition of PCBs. The Dow Chemical Company was charged by EPA on May 13, 1980, with violating the PCB regulations by manufacturing and shipping a heat transfer fluid containing monochlorinated biphenyls (MCBs). Dow fought the charge on the basis that MCBs differ from PCBs in being less hazardous, and that MCBs are not covered by the PCB regulations. Dow's challenge was denied on September 22, 1980 by EPA's Administrative Law Judge.[44]

Fully Halogenated Chlorofluoroalkanes (CFCs)

These products, commonly called chlorofluorocarbons, or CFCs, are known to react with ozone. It is believed by many scientists that continued use of CFCs will lead to a decrease in the stratospheric ozone layer which offers protection from ultraviolet rays. EPA considered the possibility of increased skin cancer and decreased crop yield to present an unreasonable risk and

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[42] *Ibid*., at p. 1097.

[43] *Ibid*., at pp. 1091, 1095 n. 47, 1093, 1095.

[44] *Chemical Regulation Reporter*, Bureau of National Affairs, September 26, 1980, p. 817.

(along with FDA) banned the manufacture, processing and use of non-essential aerosol products containing CFCs in March, 1978.[45]

In the proposed rules on aerosol uses of CFCs,[46] EPA noted that "quantitative estimates of skin cancer are somewhat speculative," but cited one estimate that "15,000 cases of nonmelanoma skin cancer during the next century would be prevented in the United States alone by banning U.S. aerosol propellant uses of these compounds in 1978." EPA estimated that the proposed restrictions on CFCs would cost industry between $169 and $267 million annually for the four year period following regulation, but that consumer savings would range from $58 to $340 million annually. The Agency stated the case for regulation as follows:

> At the price of a substantial one-time, readily absorbed economic cost which does not deprive society of essential products, a large number of threatened skin cancers and potentially serious, albeit unknown, effects on agricultural resources, climate, and the biosphere that would otherwise be suffered by future generations, would be prevented.

EPA more recently has been considering limitations on non-aerosol uses of CFCs. An advanced notice of proposed rulemaking has been published[47] outlining a variety of regulatory alternatives, including the use of economic incentives to cut production and to encourage switching to the less ozone-depleting CFCs. All CFCs would potentially be regulated by EPA (i.e. all alkanes that contain at least one chlorine and one fluorine, including CFC-11, CFC-12, CFC-113, CFC-114, CFC-115, and CFC-22), although the regulations would take into account the differing ozone depletion potential of the various CFC compounds.

Although EPA's regulations on non-essential aerosol uses of CFCs were promulgated under the authority of TSCA, it is not clear what authority will be used for regulating the nonaerosol uses. EPA stated in its advance notice that it intends to use Section 157 of the Clean Air Act unless it finds that it is in the public interest to use TSCA (Section 6).[48]

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[45] 43 FR 11318, March 17, 1978; 40 CFR 762.

[46] 42 FR 24544, May 13, 1977.

[47] 45 FR 66726, October 7, 1980.

[48] EPA is required by Sections 6(c) and 9(b) of TSCA to use other federal laws administered by EPA to eliminate or reduce risk of injury to health or environment before using TSCA, unless the Agency finds that use of TSCA is in the public interest. In using TSCA to ban the non-essential aerosol uses of CFCs, EPA determined that the Clean Air Act Amendments of 1977 "specifically permit EPA to promulgate rules proposed under TSCA prior to enactment of the Amendments" (43 FR 11319).

Asbestos

EPA has been developing a number of regulations under Section 6 to control human exposure to asbestos. In 1979 EPA published two advance notices of proposed rulemaking, covering asbestos-containing materials in school buildings[49] and commercial and industrial use of asbestos fibers.[50] In September, 1980, EPA published proposed rules for school buildings.[51]

In both these advance notices, EPA cited its concerns with the health effects of exposure to asbestos, including increased risk of lung damage (asbestosis) and several types of cancer. A finding of unreasonable risk requires consideration of the adverse health effects of asbestos, the number of people subject to exposure, the effects on the environment, the benefits of the material, and the reasonably ascertainable economic consequences of a rule.

EPA's first advance notice dealt with friable asbestos-containing material (i.e. material that crumbles under hand pressure) which is common in school buildings. No definition of asbestos is provided, and the notice seeks comments on what the Agency can do to ensure proper identification of asbestos in the absence of standard reference methods and materials. The second advance notice aimed at covering all commercial and industrial uses of asbestos, including the manufacture, processing, use, and disposal of asbestos in textiles, flooring, paints, automotive parts, etc. No definition of asbestos was provided although the notice did state that asbestos is a generic name for a variety of naturally-occurring fibrous mineral silicates (chrysotile, amosite, crocidolite, anthophyllite, tremalite, and actinolite).

In the proposed rulemaking for schools, "Asbestos" is defined as: "(1) Chrysotile, amosite, or crocidolite; or (2) in fibrous form, tremolite, anthophyllite, or actinolite." "Asbestos-containing material" means "any material which contains more than 1 percent asbestos by weight."

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[49] 44 FR 54676, September 20, 1979.

[50] 44 FR 60061, October 17, 1979.

[51] 45 FR 61966, September 17, 1980.

THE CLEAN WATER ACT--STATUTORY REVIEW

INTRODUCTION

The Clean Water Act's aim is to improve and protect the Nation's water quality. The broadly stated purpose of the legislation is "to restore and maintain the chemical, physical and biological integrity of the Nation's water" (Section 101(a)). In this context, it is the "national goal that the discharge of pollutants into the navigable waters be eliminated by 1985" (Section 101(a)(1)).[1]

The following discussion reviews what substances are subject to regulation under the Clean Water Act, what regulatory mechanisms are to be used in achieving the goals set in the Act, and what criteria must be considered in taking regulatory action.

OVERVIEW OF THE CLEAN WATER ACT

In the statutory scheme established by the Clean Water Act, three mechanisms are provided for achieving statutory goals:

- The implementation and enforcement of water quality standards (Section 303);
- The achievement of effluent limitations under which the discharges of pollutants are to be regulated (Section 301) including toxic pollutants (Section 307); and
- Provisions to control discharges of oil and hazardous substances (Section 311).

The achievement of effluent limitations is the primary means by which the water quality standards are to be achieved. However, in understanding the administrative structure of the Act, it is important to recognize the two mechanisms as distinct requirements.[2] Water quality standards control overall water quality and are analogous to the ambient air standards of the Clean Air Act. Effluent limitations regulate actual discharges for individual sources into the water.

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[1] *E. I. duPont de Nemours and Co. v. Train*, 430 U.S. 112 (1977), represents judicial endorsement of this formulation of the Clean Water Act's purpose. The Act, formally called the Federal Water Pollution Control Act, is codified at 33 USCA §§ 1251-1378. The Act was substantially revised by amendments in 1972 and 1977.

Uniform water quality standards are to be implemented in all states. Each state is to develop, submit to the EPA for approval, and implement water quality standards for water within the state boundaries. These water quality standards are to be set so as to "protect the public health and welfare, enhance the quality of water and serve the purposes of this Act" (Section 302(c)(2)).

The provisions dealing with effluent limitations state that "except as in compliance with this Act, the discharge of any pollutant by any person shall be unlawful." (Section 301(a)). This mandate is followed by a description of the methods and amounts[3] in which pollutants can be legally discharged under the Act. Effluent limitations programs are organized according to both type of pollutant and type of source. The effluent limitation provisions fall into the following categories:

(1) effluent standards for existing sources of pollution,

(2) effluent standards for new sources of pollution,

(3) effluent standards for publicly owned treatment works (POTWs), and

(4) pretreatment standards for dischargers to POTWs.

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[2] Although conceptually separate, the practical difference between the two may be quite limited. One commentator notes that the two mechanisms have been wedded judicially, citing Montgomery Environmental Coalition v. Fri, 396 F.Supp. 260 (D.D.C. 1975), where it was held "that a water quality standard could be treated as an 'effluent standard or limitation' under the citizen suit provisions (Section 505) of the [Clean Water] Act." Rogers, Handbook on Environmental Law, p. 360 (St. Paul: West Publishing Co., 1977).

[3] The method of achieving the effluent limitations is broadly described as "best practicable technology" (see §301(b)(1)) and "best available technology" (see §301(b)(2)). This terminology is to be given content by satisfying the requirements of §304(b) which involve regulations "providing guidelines for effluent limitations". These guidelines are to identify what level of control can be achieved in terms of amounts of constituents and chemical, physical, and biological characteristics of pollutants. . . ." (See §§304(b)(1)(a) and (b)(2)(A).)

Within each category there may be subcategories differentiated by type (classification) of pollutant or type of source.

Prior to 1972, there was no special provision in the Clean Water Act addressing toxic pollutants. Section 307(a) now sets forth the substantive criteria for formulating toxic effluent standards, which are not subject to individual waiver or modification as are other standards. EPA is required to take certain factors into account when issuing these standards and is directed to set these standards at levels that provide "an ample margin of safety"--a phrase that is the section's "polestar--its guiding principle in protecting against incompletely understood dangers."[*] The 1977 Amendments adopted a list of 65 groups of chemical substances for EPA to regulate and provided two separate procedures for development of standards: (1) industry-by-industry regulations based on technological feasibility criteria; (2) health-based effluent standards on a pollutant-by-pollutant basis with reference to six specific factors and an ample margin of safety. Section 307(b) and (c) provide statutory criteria for pretreatment standards for indirect discharges.

Finally, Section 311 deals with the special problems of oil and hazardous chemicals discharges. The focus, in large part, is on accidental discharges and incident reporting. This third mechanism, of course, is limited to very specific situations while the first two mechanisms are of general applicability.

Each of the provisions described above (§§ 301, 303, 307, 311) employ different statutory criteria which will be discussed as each provision is reviewed. In general, however, the Act is concerned with "pollution" of the water and the constituent "pollutants". "Pollution" is defined to mean the "man-made or man-induced alteration of the chemical, physical, biological, and radiological integrity of water" (Section 502(19)). This definition is very inclusive. The Act defines "pollutants" as "dredged spoil, solid waste, incinerator residue, sewage, garbage, sewage sludge, munitions, chemical wastes, biological materials, radioactive materials, heat, wrecked or discharged equipment, rock, sand, cellar dirt, and industrial, municipal and agricultural waste discarded into the water" (Section 502(6)). The Act, therefore has broad applicability due to the wide range of activities and substances it covers.

MECHANISMS FOR ACHIEVING THE GOALS SET BY THE CLEAN WATER ACT

The following discussion analyzes the major provisions used to meet the goals of restoring and maintaining water quality and eliminating pollutant discharges by 1985. The discussion is organized as follows:

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[*] EDF v. EPA, 12 ERC 1353, 1361 (D.C. Cir. 1978).

- a description of the provision and how it is to be applied;
- the substance(s) (for example, conventional pollutants) covered;
- the harm which the provision is supposed to ameliorate;
- the level of causality which must exist between the substance and the harm; and
- other factors (for example, cost of implementing the mechanism) which must or may be considered.

The review relies principally upon the statutory language, the Act's legislative history, and caselaw interpreting and applying the Act. Water quality standards are discussed first, followed by effluent limitations for three kinds of pollutants (conventional, toxic, and non-conventional) and Section 311 hazardous (polluting) substances conclude the review. See Exhibit 2-1.

WATER QUALITY RELATED EFFLUENT STANDARDS

The states are assigned primary responsibility to establish, implement, and enforce water quality standards. Water quality standards were first developed under the Water Quality Act of 1965. Section 303 of the Clean Water Act continues the use of water quality standards, but such standards are no longer the mainstay of achieving the Act's goals. Instead, as Section 302 indicates, water quality standards are used more in the role of substitute--when effluent limitations do not perform satisfactorily, then water quality standards are to be used. Section 302(a) requires water quality based effluent limitations to be established for a point source or group of point sources for which BAT-based limitations are not adequate to attain and maintain the water quality necessary to protect public water supplies, agricultural and industrial uses, animal life, and recreational activity. Section 302(b) requires that notice be given and hearings be held before the water quality-based limitations are set. Factors to be considered in setting these limits include the relationship between the social and economic costs and benefits, whether that relationship is reasonable, and whether the limits can be implemented with available technology or other alternative control strategies.

Water quality standards involve three elements: water quality criteria, designated uses, and an enforcement plan. Water quality criteria can be thought of as ambient water standards and may be quantitative or descriptive. An example of a quantitative standard is: "not less than 5 parts per million of dissolved oxygen or more than 500 micrograms per liter of dissolved solids or more than 200 fecal coliform per 100 milliliters." An example of a

EXHIBIT 2-1

A SUMMARY OF RELEVANT WATER POLLUTION CONTROL MECHANISMS

Control Mechanisms	Pollutants Covered	Control Standard Applied	Harm to be Avoided	Causality Criteria	Factors to Consider
1. Water Quality Related Effluent Limitations (§302)	All pollutants (defined §502(6))	Effluent limitations which can reasonably be expected to contribute to water quality unless affected person demonstrates there is no reasonable relationship between the costs and the benefits (§302(b))	Water quality which does not assure protection of public water supplies, agricultural and industrial uses, shellfish, fish, and wildlife, and recreational uses	Limitations must reasonably be expected to contribute to the attainment or maintenance of water quality	Protection of public water supplies Well-being of fish and wildlife Recreational activities in and on the water Agricultural and industrial uses
2. Effluent Standards for Existing Sources (§§ 301 and 402)	Conventional pollutants (defined §304(a)(4))	Best conventional pollutant control technology (§301(b)(2)(E))	Prevent injury to health and welfare	Mere introduction of conventional pollutant to nation's water	Informal balancing of control costs and benefits from reduced effluent Age of equipment and facilities Process being used Engineering aspects of application of various types of control techniques Process changes Nonwater quality environmental impact Other factors deemed appropriate
Effluent Limitations for Toxic Pollutants (§§ 307 and 301)	Toxic pollutants (defined §502(13))	Best available technology economically achievable (§301(b)(2), §307(a)(2)) Modifications of §301(b)(2) requirements authorized if (1) represents maximum use of technology within economic capability (2) reasonable further progress toward elimination of discharges will results. (§301(c))	Death, disease, behavioral abnormalities, cancer, genetic mutations, physiological malfunctions (including malfunctions in reproduction), or physical deformation	Pollutant will cause harm (§502 (13)) however, this is tempered by requirement that there be an ample margin of safety (§307(a)(4))	For toxic designation and standard-setting: • toxicity, persistence, degradability; usual/potential presence of affected organisms and importance of organisms; and nature and extent of effect of toxic pollutants on such organisms (§307(a)(1))

EXHIBIT 2-1 (continued)

A SUMMARY OF RELEVANT WATER POLLUTION CONTROL MECHANISMS

Control Mechanisms	Pollutants Covered	Control Standard Applied	Harm to be Avoided	Causality Criteria	Factors to Consider
2. (continued)	Toxic Pollutants (defined §502(13)) (continued)	Elimination of discharges shall be required if it is technologically and economically achievable. (§301(b)(2)(A)) Effluent standard shall be set at the level which "provides an ample margin of safety." (§307(a)(4))		Toxic effluent standard must provide an ample margin of safety.	For setting effluent limitations: • economically achievable for class of point sources • extent to which effective control is being or may be achieved under other regulatory authority (§307(a)(2)) • result in reasonable further progress toward goal of eliminating all pollutant discharges • age of equipment and facilities, process employed, engineering aspects of control techniques, process changes, cost of achieving effluent reductions, and nonwater quality environmental impact
	Non-conventional pollutants	Best available technology economically available subject to modification if no unacceptable risk imposed as a result (§301(g))	Protect water supplies, animal life and recreational activities and avoid unacceptable risks	Mere introduction of pollutants into nation's water	Bioaccumulation, persistency, toxicity or synergistic propensities
3. Effluent Standards for New Sources (National Standards of Performance) (§306)	All pollutants (defined §502(6))	Best available demonstrated control achievable (greatest degree of effluent reduction or no discharge of pollutants). (§306(a)(1))	Prevent injury to health and welfare	Mere introduction of pollutants into nation's water	Cost of reducing effluents to required level Energy requirements Type of process employed Nonwater quality environmental impacts

EXHIBIT 2-1 (continued)

A SUMMARY OF RELEVANT WATER POLLUTION CONTROL MECHANISMS

Control Mechanisms	Pollutants Covered	Control Standard Applied	Harm to be Avoided	Causality Criteria	Factors to Consider
4. Effluent Standards for Publicly Owned Treatment Works (§§ 301(b)(2)(B), 304(d)(1), and 201(g)(2)(A))	Pollutants to which the following parameters apply: • suspended solids • biological oxygen demand • pH	Secondary treatment standard or best practicable waste treatment technology over the life of the POTW	Prevent injury to health and welfare	Mere introduction of pollutants into nation's water	Alternative waste management techniques should be studied and evaluated Consistency with purposes of Title II ("to require and to assist the development implementation of waste treatment management plans and practices which will achieve the goals of this Act")
5. Pretreatment Standards (§307(b), (c))	Pollutants discharged by existing sources to POTWs	Prevent discharge of any pollutant which interferes with or passes through POTW	Not specified in statute	Discharge must interfere with or pass through POTW	
	Pollutants discharged by new sources to POTWs	Prevent discharge of any pollutant which may interfere or pass through POTW	Not specified in statute	Discharge "may" interfere with or pass through POTW	
6. Establishing liability, requiring incident reporting and clean-up (§311(b))	Oil and hazardous substances (defined §311)	No discharges (with a few few exceptions)	Imminent and substantial danger to public health and welfare, including shellfish, wildlife, shorelines, beaches, public and private property	Presents an imminent and substantial danger to the public health and welfare when discharged in any quantity	Whether discharge is accidental or result of gross misconduct

descriptive standard is "surface waters must be 'free from floating debris, scum and other floating materials attributable to municipal, industrial or other discharges or agricultural practices in amounts sufficient to be unsightly or deleterious.'" Designated uses involve classifying segments of water and defining what uses may be made of the water in a particular class. For example, water classified in Category A must be suitable for recreation, and water classified in Category B, although it may not be suitable for recreation, must be suitable for hosting and encouraging aquatic life. Enforcement plans typically involve directives to particular sources.

State plans are to be submitted to the EPA for approval. The plans are to be designed so as to "protect the public health and welfare, enhance the quality of water and serve the purposes of this Act" (Section 303(c)(2)). The standards can vary within a given state, depending on the type of use which is made of a given body of water. That is, the

> water quality standard shall consist of the designated uses of the navigable waters involved and the water quality criteria for such waters based upon such uses. Such standards shall be established taking into consideration their use and value for public water supplies, propagation of fish and wildlife, recreational purpses, and agricultural, industrial and other purposes, and also taking into consideration their use and value for navigation (Section 303(c)(2)).

The Administrator is authorized to prepare a water quality plan for any states which do not submit one. Plans are to be approved if they meet the requirements of Section 303(e)(3), the principal one being that the plan must include "effluent limitations and schedules of compliance at least as stringent as those required by Section 301" (which, as is discussed below, is the principal effluent limitation provision). Each state is also instructed to "identify waters within its boundaries for which the effluent limitations required by Section 301(b)(1)(A) and Section 301(b)(1)(B) are not stringent enough to implement any water quality standard applicable to such waters" (Section 303(a)(1)(a)). Special standards, authorized by Section 302 discussed above, are to be implemented to facilitate achievement of the quality standard applicable for these waters.

Section 304 deals in part with information that EPA is to develop regarding water quality. EPA is required (Section 304(a)(1)) to develop, publish, and revise criteria for water quality. The criteria must reflect the "latest scientific knowledge" regarding the "kind and extent of all identifiable effects on health and welfare" from pollutants in water (304(a)(1)(A)), the concentration of dispersal of pollutants or the by-products of pollutants (304(a)(1)(B)), and the effects of pollutants on biological communities (304(a)(1)(C)). Section 304(a)(2) requires the development, publication, and revision of information about the factors necessary to restore and maintain the integrity of water (304(a)(2)(A)), the factors necessary to protect animal life and recreation (304(a)(2)(B)), and measurement and classification of water quality (304(a)(2)(C)). In addition, Section 304(a)(2)(D) requires identification of those pollutants that are suitable for "maximum daily load measurement correlated with the achievement of water quality objectives."

The following points summarize the situation in which water quality related effluent standards are applied:

- The substances. Section 302 is applicable to any pollutant, including toxic pollutants. As noted earlier, the definition is broad and includes many substances that ordinarily might not be thought of as pollutants.
- The harm. The water quality related effluent limitations are to assure the attainment and maintenance of water quality standards.
- The level of causality. Water quality related effluent limitations must be reasonably expected to contribute to the attainment or mainenance of water quality standards.
- Factors to be considered. The establishment of water quality related effluent limitations is to consider several factors: the use and value of water as a public water supply; the well-being of fish and wildlife; recreation potential; agricultural and industrial uses; economic and social costs and dislocation; and use and value for navigation. In addition, setting water quality standards requires consideration of the relation between social and economic costs and benefits, whether that relationship is reasonable, and what other control technology or strategy is available.

EFFLUENT LIMITATIONS

Effluent limitations are defined in Section 502(11) of the Act. That definition indicates that effluent limitations are quantitative in nature and are applied to point sources. Effluent limitations are, therefore, more specific than water quality standards. An effluent limitation is:

> any restriction . . . on quantities, rates, and concentrations of chemical, physical, biological, and other constituents which are discharged from point sources into navigable waters, the waters of the contiguous zone, or the ocean, including schedules of compliance.

With the exception of Section 307, the Act directs EPA to establish effluent limitations and standards on an industry-by-industry basis. Within each industry, sources are required to meet different standards depending on whether they are an existing or a new source, and whether they discharge directly into a body of water (a direct discharger) or into a publicly-owned treatment work or POTW (an indirect discharger).

In addition to these distinctions, specific limitations and standards vary with the type of pollutant, of which there are three classifications:

(1) Conventional pollutants which are those identified as "classical" pollutants in the original (1974) Act. Section 304(a)(4) of the 1977 CWA identifies this class as "including but not limited to pollutants classified as biological oxygen demanding, suspended solids, fecal, coliform, and pH;"

(2) Toxic pollutants, as defined by Section 307; and

(3) Non-conventional, non-toxic pollutants which are any substances not designated as conventional or toxic.

The Act thus mandates that a specific level of pollution control technology be applied for each source and pollutant combination. Exhibit 2-2 sets out the statutory definition for each of these technology standards, and the factors which must be taken into account in identifying specific technologies as being a certain level.

The review of effluent limitations is divided into three subsections: (1) effluent standards for existing sources (conventional, toxic, and non-conventional), (2) effluent standards for new sources, and (3) effluent standards for publicly owned treatment works (POTWs), and (4) pretreatment standards.

1. Effluent Standards for Existing Sources

Section 301 establishes that effluent limitations should be promulgated for three categories of pollutants discharged from existing sources. The nomenclature for these three categories, which is more readily apparent from the regulations than the Act itself, comprises: conventional pollutants, toxic pollutants, and non-conventional pollutants. Section 301, together with Section 402, mandates establishment of a permit system through which discharges for the three categories are to be regulated. This system generally regulates discharges on an industry-by-industry basis. The substances and industries regulated by the three categories are discussed below.

Conventional Pollutants. Section 304(a)(4) identifies conventional pollutants as "including but not limited to pollutants classified as

EXHIBIT 2-2

TECHNOLOGY REQUIRED OF SPECIFIC SOURCE AND POLLUTANT TYPES

Pollutant/Source Type	Technology
I. Conventional Pollutants Existing Sources	Best conventional pollutant control technology (BCT) (Section 304(b)(4)(A)). Factors to be considered include the "reasonableness of the relationship between the costs of attaining a reduction in effluents and the effluent reduction benefits derived, and the comparison of the cost and level of reduction of such pollutants from the discharge from publicly owned treatment works to the cost and level of reduction of such pollutants from a class or category of industrial sources, and shall take into account the age of equipment and facilities involved, the process employed, the engineering aspects of the application of various types of control techniques, process changes, non-water quality environmental impact (including energy requirements), and such other factors as the Administrator deems appropriate." Section 304(b)(4)(B)
II. Toxic Pollutants Existing Sources	Best available technology economically achievable (BAT) "which will result in reasonable further progress toward the national goal of eliminating the discharge of all pollutants" by July 1, 1984 (for the 65 priority pollutants) or three years after establishment (for all other toxic pollutants listed in 307(a)(1)). Section 301(b)(2) Factors relating to the assessment of best available technology shall take into account the age of equipment and facilities involved, the process employed, the engineering aspects of the various types of control techniques, process changes, the cost of achieving such effluent reduction, non-water quality environmental impact (including energy requirements), and other such factors as the Administrator deems

EXHIBIT 2-2 (continued)

TECHNOLOGY REQUIRED OF SPECIFIC SOURCE AND POLLUTANT TYPES

Pollutant/Source Type	Technology
II. *Toxic Pollutants* Existing Sources (continued)	appropriate. Section 304(b)(2)(B) The statute thus requires a consideration of costs but does not require a balancing of costs against effluent reduction benefits. [See *Weyerhauser v. Costle*, 11 ERC 2149 (D.C. Circuit 1978)].
III. *New Sources* All Pollutants	New Source Performance Standards (NSPS) are to be based on the *"best available demonstrated technology*." Because new plants have the opportunity to install the best and most efficient production processes and wastewater treatment technologies, Congress directed EPA to consider the best demonstrated process changes, in-plant controls, and end-of-pipe treatment technologies which reduce pollution to the maximum extent feasible. Section 306(a)(1)
IV. *Pretreatment Standards* *(A) Existing Sources*	Pretreatment Standards for Existing Sources (PSES) must be achieved within three years of promulgation. PSES are designed to prevent the discharge of pollutants which *pass through*, *interfere with*, or are otherwise incompatible with the operation of POTWs. The Clean Water Act of 1977 requires pretreatment for pollutants, such as heavy metals, that limit POTW sludge management alternatives including the beneficial use of sludges on agricultural lands. The legislative history of the 1977 Act indicates that pretreatment standards are to be technology-based, analogous to the best available technology for removal of toxic pollutants.

EXHIBIT 2-2 (continued)

TECHNOLOGY REQUIRED OF SPECIFIC SOURCE AND POLLUTANT TYPES

Pollutant/Source Type	Technology
IV. Pretreatment Standards (B) New Sources (continued)	Section 307(c) requires Pretreatment Standards for New Sources (PSNS) which EPA must promulgate at the same time that it promulgates NSPS. New indirect dischargers, like new direct dischargers, have the opportunity to incorporate the best available demonstrated technologies including process changes, in-plant controls, and end-of-pipe treatment technologies, and to use plant site selection to ensure adequate treatment system installation. PSNS are designed to prevent the discharge of pollutants which may pass through, interfere with, or may be otherwise incompatible with the operation of POTWs.

biological oxygen demanding, suspended solids, fecal coliform, and pH." Section 301 calls for the achievement of effluent limitations for this category of pollutants through "application of the best conventional pollutant control technology" (§301(b)(2)(E)). Factors to be taken into account when determining the best conventional technology (BCT) are set forth in Section 304(b)(4)(B). These factors are:

> consideration of the reasonableness of the relationship between the costs of attaining a reduction in effluents and the effluent reduction benefits derived, and the comparison of the cost and level of reduction of such pollutants from the discharge from publicly owned treatment works to the cost and level of reduction of such pollutants from a class or category of industrial sources, and shall take into account the age of equipment and facilities involved, the process employed, the engineering aspects of the application of various types of control techniques, process changes, non-water quality environmental impact (including energy requirements) and such other factors as the Administrator deems appropriate.

The following points summarize the situation in which effluent limitations for conventional pollutants are applied.

- The substances involved are conventional pollutants, as described above.
- The harm to be avoided or redressed is the degradation of the Nation's waters and its resulting ill effects (both health and welfare).
- The level of causality is not specifically stated, but technically the modification of the integrity of water constitutes pollution and triggers the application of this provision.
- Factors to be considered in setting effluent limitations for conventional pollutants include some informal balancing between control costs and benefits from the effluent reduction achieved, the age of equipment and facilities involved, the process being used, and other factors deemed appropriate by EPA.

Toxic Pollutants. In Section 502(13) the term "toxic pollutants" is defined to mean:

> those pollutants, or combinations of pollutants, including disease-causing agents, which after discharge and upon exposure, ingestion, inhalation or assimilation into any organism, either directly from the environment or indirectly by ingestion through food chains, will, on the basis of information available to the Administrator, cause death, disease, behavioral abnormalities, cancer, genetic mutations, physiological malfunctions (including malfunctions in reproduction) or physical deformations in such organisms or their offspring.

The Senate Report indicated that the definition:

> provides a benchmark for evaluating those pollutants which in certain concentrations would have a particularly adverse impact on humans as well as other forms of life. It is necessary to evaluate the effect of all forms of such pollutants and consider their persistence, degradation, or interaction with other materials, once in the receiving water.

The report continued to note that

> Disease-causing agents are intended to refer to all pathogens, including viruses, which may produce disease symptoms in any organisms. In addition, any pollutant or agent which lowers an organism's resistance to serious disease should be considered a toxic pollutant. [Legislative History, Vol. 2, pp. 1495-1496.]

The 1972 amendments instructed the Administrator to list all pollutants which EPA deemed to qualify as toxic under the above definition. For a variety of reasons, implementation was slow. Environmental action groups brought four lawsuits to compel prompt regulation of toxics. EPA, in the meantime, had been developing a comprehensive strategy for dealing with toxics. The strategy was substantially adopted in a Consent Decree issued in National Resources Defense Council et al. v. Train, 411 F.Supp. 864. Under the decree, EPA was to regulate, under the toxic pollutant provision, 65 families of pollutants by 21 major sources. The 1977 Amendments essentially wrote the decree into the legislation, calling for the development of effluent limitations by July 1, 1984 for all "toxic pollutants referred to in Table 1 of Committee Print Numbered 95-30 of the Committee on Public Works and Transportation of the House of Representatives. . . ." (Section 301(b)(2)(C)).

The list is identical to that issued in the Consent Decree.[5] The Administrator also is free to list other pollutants considered toxic.[6]

Effluent limitations (or standards) for toxic pollutants are the subject of several sections in the Clean Water Act. These sections are analyzed below in light of the statutory language, legislative history, and relevant case law. The sections addressed are:

- Section 301(b)(2)(A) which requires that "best available technology" be used;
- Section 304(b)(2) which sets forth factors to be considered when adopting or revising effluent limitations that require the "best measures and practices available;" and
- Section 307(a)(1), (2), and (4) which deal with toxic effluent standards.

Sections 301(b)(2)(A) and 304(b)(2) are concerned with the imposition of best available technology[7] (BAT) for effluent controls on sources that discharge toxic pollutants. Section 301(b)(2) is the general requirement that effluent limitations applying BAT be placed on sources discharging toxic pollutants, and Section 304(b)(2) sets forth guidelines that EPA is to follow in setting these effluent limitations. These two sections and their legislative history are discussed below, followed by an analysis of how courts have dealt with the concept of BAT.

Section 301(b)(2)(A): General BAT Requirement. Section 301 deals in part with toxic pollutant effluent limitations that must be met by a certain deadline, generally by July 1, 1984. To comply, sources must apply BAT. In requiring BAT to be applied, Section 301(b)(2)(A) imposes the important qualifier that BAT must be "economically achievable" for a particular category or class of point sources. Two key characteristics of BAT are that it (1) must result in "reasonable further progress toward the national goal of eliminating the discharge of all pollutants," and (2) must require complete elimination of discharges if such elimination is "technologically and economically achievable" (as determined on the basis of information available to EPA) for categories or classes of particular point sources.

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[5] A recent case, EDF v. Costle, 14 ERC 2161 (D.C. Cir., 1980), holds that the Consent Decree remains in effect. Industry petitioners claimed that the 1977 amendments to the Clean Water Act supersede the decree, but the Court held that Congress intended the decree to remain in effect to supply the details missing in the legislative changes.

[6] As of July 1, 1979, six classes of chemical substances had been designated as toxic: aldrin/dieldrin, DDT, endrin, toxaphene, benzidine, and polychlorinated biphenyls. The effluent limitations for these pollutants are set forth at 40 CFR 129.

[7] BAT is the most strict control requirement imposed under the Clean Water Act. Its requirements, discussed later in the text, are more strict than those of the "best conventional pollution control technology."

The BAT required by Section 301(b)(2)(A) is not an absolute requirement but one to be tempered by practical consideration. For example, during the House debate on the Conference Committee Report, one of the conferees noted that when EPA identifies BAT under §301(b)(2)(A), it "must take into account energy requirements as one factor in determining the measures and practices available to comply with" the effluent limitations being set [Legislative History, Vol. 1, pp. 268-269.] This tempering or balancing becomes more apparent in light of the guidelines found in §304(b)(2).

Section 304(b)(2): Guidelines for Setting Effluent Limitations Requiring BAT. This section addresses the adoption and revision of effluent limitations and directs EPA to publish regulations that provide guidelines for effluent limitations. These regulations must:

- identify (using "amounts of constituents and chemical, physical, and biological characteristics of pollutants") the degree of effluent reduction that can be attained by applying the "best control measures and practices achievable," including (i) treatment techniques, (ii) process and procedure innovations, (iii) operating methods, and (iv) other alternatives; and

- specify factors to be considered in deciding what are the "best measures and practices available" to comply with §301(b)(2), such factors to include: (i) age of equipment and facilities, (ii) process employed, (iii) engineering aspects of control techniques, (iv) process changes, (v) costs of achieving effluent reductions, and (vi) non-water quality environmental impact.

The legislative history of this section suggests three important ground rules EPA is to follow. First, the cost of a particular technology is not determinative:

> While cost should be a factor, . . . no balancing test will be required. [EPA] . . . will be bound by a test of reasonableness. In this case, the reasonableness of what is "economically achievable" should reflect an evaluation of what needs to be done to move toward the elimination of

> the discharge of pollutants and what is achievable through the application of available technology--without regard to cost. [Legislative History, Vol. 1, p. 170.]

Second, the determination of what is BAT is not made on a case-by-case basis. Rather, it was the intention of the Conference Committee:

> that the factors described in Section 304(b) be considered only within classes or categories of point sources and that such factors not be considered at the time of the application of an effluent limitation to an individual point source within such a category or class. [Legislative History, Vol. 1, p. 172.]

Third, EPA is expected to require state of the art technology, whether currently being practiced or only demonstrated to be effective.

> In making the determination of "best available" the Committee expects [EPA] . . . to apply the same principles involved in making the determination of best practicable . . . except that rather than the range of levels established in reference to the average of the best performers in an industrial category the range should at a minimum be referenced to the best performer in any industrial category.
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> * * *
>
> As used in this bill the concept "best available control technology" is intended to mean that [EPA] . . . should examine the degree of effluent control that has been or can be achieved through the application of technology which is available or normally can be made available. This does not mean that the technology must be in actual routine use somewhere. It does mean that the technology must be available at a cost and at a time which [EPA] . . . determines to be reasonable, and that the technology has been adequately demonstrated if not routinely applied. [Legislative History, Vol. 2, pp. 1468-1470.]

What the statute and its legislative history suggest is that the determination of what is BAT should be a balancing decision best described as a "reasonable" choice. As the next section demonstrates, courts have followed this interpretation of BAT.

BAT in the Courts. The courts have addressed two important issues related to BAT--the state of the art technology required and how much weight should be given to costs.

Three cases outline what EPA's responsibilities are regarding state of the art technology.

- Tanner's Council of America, Inc. v. Train, 540 F.2d 1188 (4th Cir. 1976). The court held that EPA may look to the industry's best performer, and EPA may even assess technologies that have not been applied if there is a "reasonable basis" for believing that the technology will be available by the appropriate statutory deadline. Note, however, the court's statement: "What is a reasonable belief of today [1976] that these [best available technology standards] . . . can be achieved by 1983 would . . . not necessarily be a reasonable belief in 1981." The court indicated that as the deadline for applying the standard grew nearer, EPA would need a stronger justification for imposing its BAT standards on the leather tanning and finishing industry than required at what was then an early stage of setting the 1983 regulatory standards (at p. 1196). In general, then, as the statutory deadline for BAT draws closer, courts will expect a more precise determination of what the state of the art technology will be when the deadline arrives.

- U.S. Steel Corp. v. Train, 556 F.2d 822 (7th Cir., 1977). The court noted that a state's effluent limitations can be technology-forcing, but federal effluent limitations must be technology-based (at p. 838). Nevertheless, two later cases in different circuits (BASF Wyandotte Corp. v. Costle, 598 F.2d 637, 646-651 (1st Cir. 1979) and Weyerhaeuser Company v. Costle, 590 F.2d 1011 (D.C. Cir., 1978) suggest that EPA has some technology forcing authority.[a]

- Hooker Chemicals and Plaxtics Corp. v. Train, 537 F.2d 620 (2d Cir. 1976). The court determined that, although a pollution control device can be considered "available" even though no plant in a given industry has adopted it, the administrative record compiled by

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[a] The "technology forcing" is somewhat limited, and seems to apply primarily to industrial categories that are uniformly deficient in their control practices. The extent of technology forcing permitted for these categories is apparently limited to what is being utilized in other industrial categories. This is not a strong version of "technology forcing".

> EPA must support the conclusion that such technology is both "feasible" and "reasonably . . . expected" to provide the required effluent reduction when applied to a particular industry (at p. 636).

Other cases support the notion that cost considerations are not dispositive in the determination of what constitutes BAT. Three cases are noted below:

- American Meat Institute v. EPA, 526 F.2d 422 (7th Cir., 1975). Although EPA is not required to perform a formal cost-benefit analysis, it still must consider costs in determining what is BAT (at p. 462-463).
- American Iron and Steel Institute v. EPA, 526 F.2d 1027 (3d Cir., 1975).[9] In determining "best available technology economically achievable," the court held that compliance cost was not of primary importance (at p. 1051).
- FMC Corp. v. Train, 539 F.2d 973 (4th Cir., 1976). The Court noted that Congress "has determined that many intangible benefits of clean water justify vesting [EPA] . . . with broad discretion, just short of being arbitrary or capricious, in [its] . . . consideration of cost of pollution standard" (at p. 979).

Although cost of compliance is not meant to be a determinative factor in setting BAT, Section 301(c) does allow variances to BAT to be issued to individual point sources, and cost of compliance is one factor to be considered in issuing a variance. The Supreme Court recently settled a controversy about the granting of variances from the control standard imposed under BPT and BAT.[10] Section 301(c) allows EPA to vary the requirements of BAT with respect to an individual point source (note that BAT is set at a uniform level for categories and classes of point sources) if (1) the variance represents "the maximum use of technology within the economic capability of the" source and (2) the variance "will result in reasonable further progress" toward eliminating pollutant discharge.[11]

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[9] Motions granted 560 F.2d 589, 568 F.2d 284, cert. den. 435 U.S. 914.

[10] See EPA v. National Crushed Stone Association, 49 Law Week No. 22, pp. 4008-4013 (December 2, 1980).

[11] One lower court had interpreted this provision to be applicable to variances from BPT as well--that the individual source's ability to pay for the required BPT could be taken into account. The Supreme Court rejected this view and held that the economic situation of an individual point source's owner or operator could be a factor only in BAT variances.

Summary of BAT. The BAT requirements in Sections 301(b)(2) and 304(b)(2) are not absolute in nature. EPA, in its determination of what constitutes BAT, is to take a reasonable approach. The reasonable approach should take into consideration the cost of control and characteristics of the industry for which BAT is being determined. Nevertheless, the overall goal of effluent limitations is to achieve complete elimination of discharges.

Section 307: Toxic Effluent Standards.[12] Section 307(a) sets forth important guidelines for EPA to follow in setting toxic effluent standards. Three of these guidelines are discussed below.

(1) Section 307(a)(1) sets forth both what substances are to be included on a list of toxic pollutants and what factors are to be considered in adding to or subtracting from this list. The factors to be considered in revising the list include: (i) toxicity of the pollutant; (ii) persistence; (iii) degradability; (iv) usual or potential presence of affected organisms in any waters; (v) importance of affected organisms; and (vi) nature and extent of effect of toxic pollutants on such organisms. EPA decisions under Section 307(a)(1) are subject to judicial review applying the "arbitrary and capricious" standard--a standard that gives the agency great discretion.

(2) Section 307(a)(2) indicates that substances on the toxic pollutants list are subject to effluent limitations based on "best available technology economically achievable for the applicable category or class of point sources" as established by Sections 301(b)(2)(A) and 304(b)(2). EPA may, in its discretion, promulgate an effluent standard for toxic pollutants "which, if an effluent limitation is applicable to a class or category of point sources, shall be applicable to such category or class only if

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[12] "Effluent standards" and "effluent limitations" seem to be used interchangeably. One commentator notes that "[t]he Act defines an effluent limitation [in section 502(11)] consistently with the conventional understanding of an effluent standard. . ." Rogers, op. cit., p. 451. As used in Section 307(a), the "limitation" can be thought of as applying to a category of source, and a "standard" can be thought of as applying to a particular pollutant.

> such standard" is stricter.[13] In setting such an effluent standard (which can include a prohibition), EPA must take into consideration: (i) toxicity of the pollutant; (ii) the persistence of the pollutant; (iii) the degradability of the pollutant; (iv) the usual or potential presence of affected organisms in any waters; (v) the importance of such affected organisms; (vi) the nature and extent of the effect of toxic pollutants on such organisms; and (vii) the extent to which effective control is being or may be achieved under other regulatory authority. A standard promulgated under Section 307(a)(2) is subject to judicial review based on the "substantial evidence" test--a harder test to satisfy than the "arbitrary and capricious" test by which decisions on adding to or subtracting from the toxic pollutant list are judged.[14]

(3) Section 307(a)(4) requires that any effluent standard promulgated under 307 "be at that level which [EPA] . . . determines provides an ample margin of safety."

Legislative History of Section 307. The legislative history of the section indicates that there were two significant concerns about the standard setting authorized. First, toxicity is dependent, at least in part, on the interaction of the pollutant with the water into which it is discharged.

> [T]he toxicity of some "pollutant" will depend upon the species or valence of the pollutant present in any discharge.[15] [When this is so] . . . , it is expected

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[13] This provision of Section 307(a)(2) deals with two distinct control strategies. First, effluent limitations may be set for categories or classes of point sources. These limitations would apply to any pollutant emitted from that point source. Second, an effluent standard can be set for a particular toxic pollutant; regardless of what kind of point source emitted this toxic pollutant, the standard would apply. Section 307(a)(2) indicates that toxic pollutants will be subject to the BAT standard generally applicable to the point source from which it is emitted unless EPA promulgates a toxic pollutant-specific standard that is stricter than the emission limit already applicable. The stricter standard takes precedence over the pre-existing emission limitation.

[14] The reason for the stricter standard is due to relative severity of what each section authorized EPA to do--under 307(a)(1) EPA considers only the appearance of a substance on a list, under 307(a)(2) EPA can ban discharge of the substance.

[15] The terms "species" and "valence" refer to the makeup of an atom of the pollutant and affect how the pollutant reacts to its environment.

> that standards should be set in terms of the specific species or valence. Care should be taken, however, to be reasonably assured that physical, chemical or biological processes in the receiving waters will not cause changes in the species or valence. [Legislative History, Vol. 1, p. 799.]

Second, the House Report made it very clear that the costs of compliance were, at best, a secondary consideration in setting effluent standards for toxic pollutants.

> Less stringent standards for an industry will not be established simply because it is more expensive to treat wastes to eliminate or reduce toxic discharges in one industry than in another. The Committee considers that the discharge of toxic pollutants are [sic] much too dangerous to be permitted on merely economic grounds. [Ibid., pp. 799-800.]

Case Law. The case law generally indicates that determinations of toxicity and the need for effluent limitations or standards are within the expertise of EPA, and the courts will not disturb a decision by the Agency that is based on substantial evidence.[16]

Summary. The following points summarize the situation in which effluent limitations for toxic pollutants are applied.

- The substances involved are toxic pollutants as defined in Section 502(13).
- The harms to be avoided also are noted in Section 502(13): death, disease, behavioral abnormalities, cancer, genetic mutations, physiological malfunctions (including malfunctions in reproduction) or physical deformations.

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[16] See e.g., EDF v. EPA, 598 F.2d 62 (D.C. Cir. 1978) upholding EPA's PCB regulations; Hercules, Inc. v. EPA, 598 F.2d 91 (D.C. Cir. 1978) upholding EPA's effluent standards for toxaphene and endrin. The substantial evidence test requires a reviewing court to defer to the agency's choice between "two fairly conflicting views," even where the court would have been justified in reaching the opposite conclusion if the court were hearing the case as the trier of fact. (EDF court citing Universal Camera Corp. v. NLRB, 340 U.S. 474, 488 (1951)). In Hercules, the court noted that in reviewing a numerical standard "we must ask whether the agency's numbers are within a 'zone of reasonableness,' not whether its numbers are precisely right" (at p. 107).

- The level of causality seems to be fairly high. The pollutant is considered toxic only if, on the basis of information available to EPA, it will cause the harms mentioned above. This appears to require EPA to have more than a suspicion or reasonable doubt about the toxicity of a pollutant. That the agency must have a scientific basis for determining that the pollutant will cause the harm, however, is not necessarily the intent of the Act. In EDF v. EPA, supra, the court noted that "the 'ample margin of safety' provision [Section 307(a)(4)] directs EPA to guard against incompletely known dangers." The Court specifically disagreed with an industry contention "that EPA must demonstrate the toxicity of each chemical it seeks to regulate through studies demonstrating a clear line of causation between a particular chemical and harm to public health or the environment" (at p. 83). In that case the court upheld EPA's use of information about more chlorinated PCBs as the basis for regulating less chlorinated PCBs (about which little was known).

- Factors to be considered in dealing with toxic pollutants are numerous. These factors can be divided into two broad categories: factors to be considered in designating a pollutant as "toxic" and factors to be considered in setting effluent limitations for particular toxic pollutants. In the former category such factors as the pollutant's toxicity, persistence, and degradability are to be considered. The latter category includes such added factors as whether the standard is economically achievable for a class of point sources, the age of equipment and facilities, and the engineering aspects of control techniques.

Because the harm involved in this situation is more severe than in previously discussed situations, the measures (notably BAT) to guard against this harm are correspondingly more strict. The level of causality, however, which must be found before these stricter measures are justified is also more difficult to satisfy.

Non-Conventional Pollutants. Non-conventional pollutants are the third category of pollutant for which effluent standards are issued for existing sources. This category includes any pollutant not classified as conventional or toxic. Under Section 301, discharges of these pollutants are to be limited by July 1, 1987 at the latest to levels achievable through the application of the "best available technology economically achievable (BAT)". BAT is defined here as it was above for toxic pollutants.

This catch-all category might be expected to be large, but EPA currently regulates less than ten "non-conventional" pollutants. Some non-conventional pollutants, however, are widely discharged. While a limited number of pollutants are regulated under this provision, a large number of industries[17] are subject to regulation because of their discharge of non-conventional pollutants.

Section 301(g) allows non-conventional pollutant point sources to obtain modification of the BAT requirements imposed by Section 301(b)(2)(A). This modification is based on water qualify considerations (unlike the Section 301(c) modification which is based on economic considerations). The granting of this modification depends on several factors: (1) the modification must, at a minimum, satisfy the requirements of BPT or, in some instances, stricter limitations (301(g)(1)(A)); (2) the modifications must not place additional burdens on other point or nonpoint sources (301(g)(1)(B)); and (3) the modification cannot interfere with attainment or maintenance of that water quality necessary to protect public water supplies, animal life, recreational activities, and "will not result on the discharge of pollutants which may reasonably be anticipated to pose an unacceptable risk to human health or the environment because of bioaccumulation, persistency in the environment, acute toxicity, chronic toxicity (including carcinogenicity, mutagenicity or teratogenicity), or synergistic propensities" (301(g)(1)(C) emphasis added).

The following points summarize the situations in which effluent limitations for non-conventional pollutants from existing sources are applied.

- The substances involved are non-conventional pollutants, defined above.
- The harm to be avoided is the discharge of pollutants in quantities which may reasonably be anticipated to pose an unacceptable risk to human health or the environment due to bioaccumulation, persistency, or toxicity.
- The level of causality is not explicit, but it is clear that the modification of the integrity of water constitutes pollution and triggers the application of the effluent limitations. In deciding whether a particular point source will be granted a modification from BAT requirements, discharges cannot be permitted that "may reasonably be anticipated to pose an unacceptable risk."

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[17] They are listed at 40 CFR 122, Appendix A.

- Factors to be considered in setting the standards are detailed above and include costs of achieving the required effluent reduction, age of equipment and facilities, and nonwater quality environmental impacts. In allowing a modification, EPA must consider a pollutants' bioaccumulation, persistence, toxicity, and synergistic propensities.

2. Effluent Standards for New Sources--National Standards of Performance[18]

To further achieve the water quality standards elaborated under Section 303, the administrator is authorized to set National Standards of Performance for all new sources of water pollution. These standards would be similar to those demanded by effluent limitations, but could be set at different levels depending on the economics of new source pollution control versus retrofit pollution control. Under this provision, the Administrator is to promulgate standards for new pollution sources on an industry by industry basis. In the 1977 Amendments, 27 industries were identified for which the Administrator was to promulgate standards. See Section 306(b)(1)(A). The standards of performance were to be set at levels which reflect "the greatest degree of effluent reduction which the Administrator determines to be achievable through application of the best available demonstrated control technology, processes, operating methods, or other alternatives including where practicable, a standard permitting no discharge of pollutants" (Section 306(a)(1)). The Administrator is to take into account "the cost of achieving such effluent reduction, and any non-water quality environmental impact and energy requirements" (Section 306(b)(1)(B)).

The situations for applying national standards for performance to new sources can be summarized as follows:

- The substances being regulated are "pollutants" as defined in Section 502(6) and which are the general concern of the Act.

- The harm involved and to be avoided is that generally associated with the degradation of the nation's waters--ill effects on health and welfare.

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[18] The new source performance standards are distinct from the standards to be set for existing sources. Existing sources are subject to a two-step process, BPT and BAT, while new sources are expected from the beginning to make a maximum effort to control pollutant discharges.

- The level of causality which must exist between the harm and the substance regulated, as with most other sections, is not specifically articulated. Technically, the mere introduction of the pollutant into water is all that is necessary to trigger the application of this section.

- Factors to be considered in setting national standards of performance include the cost of reducing effluents to the level required and nonwater quality environmental impacts.

3. Effluent Standards for Publicly Owned Treatment Works

Publicly owned treatment works (POTWs) are not subject to the effluent limitations of Section 301. Instead, POTWs are to comply with limits set by the administrator under Section 304(d)(1). The Administrator is to publish "information in terms of amounts of constituents and chemical, physical, and biological characteristics of pollutants, on the degree of effluent reduction attainable through the application of secondary treatment" (Section 304(d)(1)). The secondary treatment standards, defined in terms of three parameters (suspended solids, pH, and biochemical oxygen demand),[19] were to have been met by July 1, 1977. Secondary treatment standards, therefore, are based on traditional water quality parameters, whereas effluent limitations applicable to private sources are based on specific pollutants.

By July 1, 1983, Section 301(b)(2)(B) mandates that POTWs are to satisfy the requirement of Section 201(g)(2)(A) that there be in use "the best practicable waste treatment technology over the life of the works." Section 201 suggests that determining what "best practicable technology" entails requires consideration of all environmental conditions relevant to a specific proposed water treatment plant. In addition, this determination requires consideration of alternative treatment techniques and consistency with the purposes of Title II of the Act. This interpretation was upheld in Environmental Defense Fund Inc. v. Costle, 439 F. Supp. 980 (D.C.N.Y., 1977). Privately owned pollutors are to comply with the pretreatment controls of Section 307 if they discharge pollutants into a POTW.

4. Pretreatment Standards

Sections 307(b) and (c) provide for the establishment of pretreatment standards for sources of pollutants that pass through or interfere with the operations of POTWs. Pretreatment standards are to be established for categories of both existing sources and new sources simultaneously. The statutory criteria for such standards are virtually identical with one exception. For new sources, pretreatment standards are to be promulgated for pollutants which "may" interfere or pass through POTWs; for existing sources, only a pollutant which in fact "interferes with or passes through" POTWs are subject to pretreatment standards.

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[19] The rules applicable to POTWs are set forth at 40 CFR 133. This section describes the minimum water quality level to be attained by the "secondary treatment" provided by POTWs for these three parameters.

Finally, with respect to toxic pollutants covered by Section 307(a), pretreatment standards for existing sources may be revised to reflect the removal of toxic pollutants by the POTWs. To qualify, the discharge from POTWs must not violate the effluent standard or limitation which would apply to a direct discharger (§307(b)(1)).

OIL AND HAZARDOUS SUBSTANCES

The third mechanism provided for achieving the goals of the Clean Water Act is found in Section 311 which prohibits discharges[20] of "oil and hazardous substances." Oil is defined in the Act to mean "oil of any kind or in any form including, but not limited to petroleum, fuel oil, sludge, oil refuse, and oil mixed with wastes other than dredged spoil. . . ." (Section 311(a)). A hazardous substance is one which presents "an imminent and substantial danger to the public health or welfare, including, but not limited to, fish, shellfish, wildlife, shorelines, and beaches" (Section 311(b)(2)(A)).[21]

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[20] "Discharges" is defined to include "any spilling, leaking, pumping, pouring, emitting, emptying or dumping" (Section 311(a)(2)), but excluded from this definition are three discharge situations related to permits issued under Section 402:

(1) discharges that are in compliance with a permit issued under Section 402;

(2) discharges that result "from circumstances identified and reviewed and made a part of the public record with respect to a permit issued or modified" under Section 402, and that also are subject to a condition in such permit; and

(3) continuous or anticipated intermittent discharges from a point source "that are identified in a permit or permit application under Section 402" and that "are caused by events occurring within the scope of relevant operating or treatment systems".

Administrative responsibility in this area is assigned to the President. The President is required to determine "those quantities of oil and any hazardous substances the discharges of which . . . may be harmful to public health or welfare of the United States" (Section 311(b)(4)). Any discharge (either intentional or unintentional) of any oil or other hazardous substances in amounts equal to or greater than those cited as reportable is prohibited. While authority to institute requirements designed to prevent such discharges is present under this section, the provisions concentrate in large part on incident reporting and clean-up liability for spills which do occur.

Many chemicals have been designated as "hazardous".[22] Most but not all of the substances designated as hazardous under Section 311 have also been designated as conventional, toxic, or non-conventional pollutants for effluent limitation purposes. The reason for the dual designation is that the focus of Section 311 deals with discharges (generally discrete events that are accidental) that pose "an imminent and substantial danger to the public health or welfare;" effluent limitations relate more to discharges that occur as a normal part of ongoing activities by the discharger. Section 311 is concerned primarily with preventing and ameliorating the discharge of hazardous substances, and, consequently, it deals with the issues of liability, incident reporting, and clean-up. Section 311(b)(4) requires regulations to be promulgated that establish at what quantity a hazardous substance may be harmful to the public health or welfare; any discharge at or in excess of these quantities is prohibited except "in quantities and at times and locations or under such circumstances or conditions as [determined] . . . by regulation . . . not to be harmful" (Section 311(b)(3)). In addition, chemicals identified as "hazardous" but which meet the permit requirements of Section 402 are specifically excluded from regulations under Section 311 (Section 311(a)(2)).

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[21] The "Comprehensive Environmental Response, Compensation, and Liability Act of 1980" (Superfund) was enacted on December 3, 1980. It contains provisions governing situations involving hazardous substances that are addressed under Section 311 of the Clean Water Act. Although the Superfund legislation apparently does not completely pre-empt Section 311's authority, the Superfund Act does take precedence if it conflicts with a provision of Section 311 (see Section 304(c) of the Superfund Act). See the statutory review of Superfund in Chapter 8 of this volume.

[22] These designations are found in 40 CFR 116. See CWA regulatory review for further discussion.

Authority to establish preventative measures is created by Section 311(j). Here the Act calls for regulations "establishing procedures, methods, and equipment and other requirements for equipment to prevent discharges of oil and hazardous substances from vessels and from onshore facilities and offshore facilities, and to contain such discharges" (Section 311(j)(1)(B)). This authority has since been delegated in part to the EPA and in part to the Coast Guard under Executive Order 11735.[23]

If a discharge does occur, the person in charge of the vessel or facility is to "immediately notify the appropriate agency of the United States of such discharge" (Section 311(b)(5)). Persons failing to provide notification are subject to fine or imprisonment. The President is to establish a National Contingency Plan for the mitigation and removal of discharges. The owner of the vessel or facility from which the discharge occurs is liable for costs incurred in removal and restoration of natural resources damaged by the discharge up to the limits specified in the Act.

The situations in which the regulations under Section 311 are invoked are summarized below:

- The substances being regulated are oil and hazardous substances as defined in the section.
- The harm generally to be avoided is an "imminent and substantial danger to the public health and welfare".
- The level of causality involved with designating hazardous substances is "presents an imminent and substantial danger to the public health or welfare". The use of "present" suggests that the causal link need not be irrefutably determined. This is in contrast to the definition of "toxic substances" (§502(11)) for which the causal link must be more surely established. The establishment of reportable quantities is contingent on the "may be harmful" criterion.
- Factors to be considered in designating substances as "hazardous" include whether the substance imminently and substantially endangers "fish, shellfish, wildlife, shorelines, and beaches," and other aspects of the "public health and welfare." There is a statutory mandate that there are to be no discharges of oil or hazardous materials; the absolute nature of this policy (see Section 311(b)(1)) indicates that consideration of costs does not enter into the designation of a substance as "hazardous."

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[23] 38 Federal Register 21243 (1973). EPA regulations are at 50 CFR 112. Coast Guard regulations at 33 CFR 154-156.

THE CLEAN WATER ACT--REGULATORY REVIEW

INTRODUCTION

The following discussion reviews the regulations designating hazardous substances under the Clean Water Act (CWA). The discussion is organized into three sections:

(1) Effluent Limitations, Performance, and Pretreatment Standards,

(2) Toxic Pollutant Effluent Standards, and

(3) Discharges of Hazardous Substances

The first section describes pollutants which are regulated (see 40 CFR 405-460) based exclusively on technological controls. Effluent limitations are required by Section 301 of the CWA for conventional, toxic, and non-conventional pollutants. New source performance standards for regulating all pollutants at the point of discharge are reviewed. In addition, pretreatment standards promulgated under Section 307(b) and (c) for discharges into a publicly-owned treatment work (POTW) are included. The methods EPA uses to establish the standards and the types of pollutants controlled in each case are examined.

The next section reviews effluent standards for toxic pollutants based on toxicological factors as well as economic and technological feasibility. Toxic Pollutant Effluent Standards, 40 CFR 129, are promulgated under Section 307 of the CWA and are intended to control pollutants which EPA determines pose serious environmental threats. Toxic Pollutant Effluent Standards are applicable to pollutants emitted from point sources regulated under Section 301 of the CWA (effluent limitations for toxic pollutants) only if the standards promulgated under Section 307 are more stringent.

The final section examines chemicals designated as "hazardous substances" under Section 311 of the CWA. Toxicological characteristics and discharge potential are the two principal criteria EPA relies on to designate these substances as hazardous. The regulations authorized by Section 311, 40 CFR 116-117, establish reportable quantities for all designated hazardous substances. The methodology EPA employs to determine those quantities of hazardous substances which, when discharged, "may be harmful" to the public health or welfare is reviewed.

EFFLUENT LIMITATIONS AND PERFORMANCE AND PRETREATMENT STANDARDS--REGULATORY REVIEW

The effluent limitations required by Section 301 of the CWA and other performance standards are the primary mechanisms for regulating pollution at the point of discharge, as well as the means by which national water quality standards are to be achieved, as discussed in detail in the Statutory Review.

Section 301 (a) of the CWA states that "except as in compliance with this Act, the discharge of any pollutant by any persons shall be unlawful." The exceptions are defined in subsequent sections by the level of technology required of various classes of dischargers for specific types of pollutants. It is up to EPA, however, actually to identify a given technology as the "best available," "best practicable," etc. Specifying a pollution control process as representing a certain level of abatement does not require all sources to install that technology, as EPA has declared specifically in all the regulations proposed through 1980:

> The proposed regulations do not require the installation of any particular technology. Rather, they require achievement of effluent limitations representative of the proper application of these technologies or equivalent technologies. [Emphasis added.]

Thus, if a best available technology (BAT) control process is identified which limits total zinc discharged to 0.07 pounds per 1000 pounds of finished product,[1] a regulated source may use any controls or combination of controls which achieve the specified limitation.

Section 306(b)(1)(A) of the 1974 Act directed EPA to publish effluent guidelines and performance standards for, at a minimum, twenty-seven specific industrial categories. Regulations for these sources and an additional sixteen categories designated by EPA were published between May, 1974 and

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[1] The effluent limitations for BPT, BCT, BAT and NSPS are generally expressed as mass limitations (lbs/1.000 lbs raw material) and are calculated by multiplying three figures: (1) effluent concentrations determined from analysis of control technology performance data, (2) wastewater flow for each subcategory, and (3) any relevant process or treatment variability factor (e.g., maximum month vs. maximum day). This basic calculation was performed for each regulated pollutant or pollutant parameter for each subcategory of an industry. Effluent limitations for PSES and PSNS are generally expressed as allowable concentrations in milligrams per liter (mg/1).

June, 1976. Exhibit 2-3 presents a chronology of the effluent guidelines, performance and pretreatment regulations promulgated through January 1981. The primary emphasis in this round of rule-making was placed on identifying and achieving the best practicable technology (BPT) to control conventional pollutants in each of the regulated industries.

The 1977 Amendments shifted the focus of the CWA away from conventional pollutants and on to toxic pollutants, specifically the sixty-five priority pollutants identified in the 1976 Settlement Agreement. Moreover, the BPT requirements of the 1974 Act were replaced by the goal of achieving, by July 1, 1984, the "best available technology economically achievable" (BAT), in the twenty-one priority industries specified in the 1976 Settlement Agreement. Achievement of BAT, according to EPA, is the first step in making reasonable further progress toward the national goal of eliminating the discharge of all pollutants. The remainder of this analysis will focus on this latest round of regulations required by the 1977 Amendments.

As of January 1981, EPA has proposed effluent guidelines and performance and pretreatment regulations for ten of the twenty-one priority industries specified in the 1977 Amendments and listed in Exhibit 2-4. A review of these proposed standards (none of which had been promulgated as final rules) highlights certain points which should be mentioned at the outset of this discussion.

- First, as directed by the CWA, the standards are wholly technology-based. There is no indication in any of the Preambles or other supporting documentation that the Agency specifically considered differential health or other effects in determining the levels of control required. Proposed standards simply reflect the effluent limitations achievable under a particular level of technological controls.

- Secondly, the shift in emphasis from conventional to toxic pollutants is evidenced by the fact that, of the pollutants selected for regulation, the majority are known to have acute or chronic toxic or carcinogenic effects. Far more effort has been given to the regulation of these substances than to the classical pollutants and pollution parameters.

- Finally, the most-cited factor used to identify abatement technologies as representing a particular level of control has been that of "reasonable cost". Although the term is interpreted somewhat differently from standard to standard (as will be discussed in greater detail below), consideration of this factor appears to be essential in establishing both effluent guidelines and performance standards.

EXHIBIT 2-3

REGULATORY CHRONOLOGY: EFFLUENT LIMITATIONS, PERFORMANCE AND PRETREATMENT STANDARDS

DATE	EPA REGULATORY ACTION	REFERENCE
May 1974 to June 1976	EPA Proposed and Promulgated Effluent Guidelines for 27 Industrial Categories	Codified at 40 CFR Parts 405-460
July 28, 1978	Designations and Proposed Additions to Conventional Pollutants List	43 FR 32857
July 2, 1979	Proposed Effluent Guidelines, Performance and Pretreatment Standards for Leather Tanning and Finishing Industries	44 FR 38746
July 30, 1979	Final Rule Identifying Conventional Pollutants	44 FR 44501
August 29, 1979	Final Rule Establishing BCT to Replace BAT for Thirteen Industries, and Withdrawing BAT for Certain Sub-Categories of These Industries	44 FR 50732
October 29, 1979	Proposed Effluent Guidelines, Performance and Pretreatment Standards for Textile Mills	44 FR 62204
October 31, 1979	Proposed Effluent Guidelines, Performance and Pretreatment Standards for Timber Processing Plants	44 FR 62810
November 29, 1979	Proposed Effluent Guidelines, Performance and Pretreatment Standards for Gum and Wood Chemicals	44 FR 68710
December 21, 1979	Proposed Effluent Guidelines, Performance and Pretreatment Standards for Petroleum Refining Facilities	44 FR 75926

EXHIBIT 2-3

REGULATORY CHRONOLOGY: EFFLUENT LIMITATIONS, PERFORMANCE AND PRETREATMENT STANDARDS
(CONTINUED)

DATE	EPA REGULATORY ACTION	REFERENCE
January 3, 1980	Proposed Effluent Guidelines, Performance and Pretreatment Standards for Paint Formulating Facilities and Ink Formulating Facilities	45 FR 912 45 FR 928
July 24, 1980	Proposed Effluent Guidelines, Performance and Pretreatment Standards for Inorganic Chemical Producers	45 FR 49450
October 14, 1980	Proposed Effluent Guidelines, Performance and Pretreatment Standards for Steam Electric Power Plants	45 FR 68328
December 1, 1980	Petition by American Iron and Steel Institute to Add Ammonia and Sulfide to Conventional Pollutant List Denied by EPA	45 FR 79694
December 15, 1980	Portions of Effluent Guidelines for Phosphate Manufacturing and Meat Products Revoked by EPA in Response to Seventh Circuit Court Decision to Remand These Guidelines to EPA [American Meat Institute v. EPA, 526 F.2d 442 (7th Cir. 1975)]	45 FR 82253
January 6, 1981	Proposed Effluent Guidelines, Performance and Pretreatment Standards for Pulp, Paper, and Paperboard Builders' Paper and Board Mills	46 FR 1430

EXHIBIT 2-4

TWENTY-ONE PRIORITY INDUSTRIES IDENTIFIED IN 1977 SETTLEMENT AGREEMENT

Timber products processing

Steam electric power plants

Leather tanning and finishing

Iron and steel manufacturing

Petroleum refining

Inorganic chemicals manufacturing

Paving and roofing materials

Paint and ink formulation and printing

Soap and detergent manufacturing

Auto and other laundries

Plastic and synthetic materials manufacturing

Textile mills

Organic chemicals manufacturing

Nonferrous metals manufacturing

Pulp and paperboard mills and converted paper products

Rubber processing

Miscellaneous chemicals

Machinery and mechanical products

Electroplating

Ore mining and dressing

Coal mining

STANDARD-SETTING METHODOLOGY

The preambles to the eight proposed regulations set forth the process by which the Agency evaluates pollution control techniques as fulfilling a certain level of technology. This process, in broad terms, entails six basic steps.

(1) Data on the industry to be regulated was gathered, including number of firms; size, age, physical configuration and location of plants; control equipment in use in various types of plants; and economic data on the industry. Based on these data, industries were divided into sub-categories reflecting key shared characteristics, and regulations were established for each sub-category.

(2) Effluent specimens from a sample of firms were taken and analyzed for pollutants. These samples were compared to concentrations from intake sources to determine the contribution of the industrial process to wastewater concentrations.

(3) Because the 65 pollutants and classes of pollutants included thousands of specific substances, EPA selected 129 pollutants for study in these industry rulemakings. The criteria for selection of the 129 included frequency of occurrence in water, chemical stability and structure, amount of the chemical produced, and availability of chemical standards for measurement. These pollutants are discussed further below.

(4) The wastewater samples collected from each of the industry sources were then analyzed for the presence of any of the 129 specified polutants, using analytical methods identified by EPA scientists who considered "their sensitivity, laboratory availability, costs, applicability to diverse waste streams from numerous industries, and potential for implementation within the statutory and court-ordered time constraints. . . ."[2]

(5) Effluent limitations and performance standards were calculated from the assembled data on wastewater concentrations, industry profiles, and the cost and availability of various control technologies. This process was repeated for each of the standards and guidelines required by the Act.

(6) EPA's criteria documents for the 129 pollutants in question served as the basis for establishing "safe" concentrations. Effluent limitations are calculated against these safe concentration, using the assembled data on wastewater concentrations, industry profiles, and cost and availability of various control technologies.

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[2] This explanation is included in the Preambles to all of the proposed regulations. See, e.g., 44 FR 38746 (proposed regulations for leather tanning industry).

EFFLUENT LIMITATIONS FOR CONVENTIONAL POLLUTANTS

Section 304(a)(4), included in the 1977 Amendments, identifies conventional pollutants "including but not limited to pollutants classified as biological oxygen demanding, suspended solids, fecal coliform, and pH." Section 301 calls for the achievement of effluent limitations for this category of pollutants through "application of the best conventional pollutant control technology." Factors to be taken into account when determining the best conventional control technology (BCT) "include consideration of the reasonableness of the relationship between the costs of attaining a reduction in effluents and the effluent reduction benefits derived, and the comparison of the cost and level of reduction of such pollutants from the discharge..." (Section 304(b)(4)(B)).

The BCT requirement replaces the 1974 mandate for installing the "best available technology economically achievable" to control conventional pollutants. Again, this change in required control technology reflects the focus of the 1977 Amendments, which shifted the emphasis from control of "classical" (conventional) pollutants to control of toxic substances.

Conventional pollutants are nowhere defined explicitly in the CWA: EPA was therefore given broad discretion in determining the criteria it would employ. EPA issued a proposal for the "Identification of Conventional Pollutants" on July 28, 1978 [43 FR 32857] and a final rule was published July 30, 1979 [44 FR 44501]. The proposed rule outlined the criteria used to identify substances as conventional pollutants (or pollution parameters) and listed chemical oxygen demand (COD), phosphorus, and oil and grease as possible additions to the conventional pollutants set forth in the CWA. Four criteria were examined, two of which were ultimately selected:

- The major consideration in the selection process was the "environmental effects" of classes of pollutants. EPA reviewed the legislative history of the Act, which indicated that conventional pollutants were generally "naturally occurring, biodegradable, oxygen-demanding materials, and solids [sic] and which have similar characteristics to naturally occurring biodegradable substances." Since these characteristics impact water quality and aquatic life, they were therefore deemed an appropriate selection criterion.

- The second criterion established by the Agency was the designation of those pollutants which traditionally have been the primary focus of wastewater control. This action was supported by the Act's specification of pH and fecal coliform, both of which have been widely-used indicators of overall water quality.

- Because the cost and level of reduction of conventional pollutants from the discharge of POTWS is one factor used to establish the "reasonableness" of BCT limitations, EPA considered using treatability by a POTW as a selection criterion. The concept of secondary treatment was nowhere identified by Congress as a requirement in defining the reasonableness test, however, and EPA therefore determined that it should not be included as a necessary criterion for selection.

- The fourth criterion considered was that conventional pollutants be only those not identified as toxic. The Agency decided, however, that toxic properties were not sufficient to preclude a substance from identification as a conventional pollutant. Moreover, EPA believes it has been given the flexibility to weigh a substance's toxic and conventional properties and assign that substance to the list it deems more appropriate. The major impact of assigning a pollutant to one or the other list is that conventional pollutants require BCT limitations, while toxic pollutants must meet BAT; the level of control for a conventional pollutant may therefore be less stringent.

The conventional pollutants required by the CWA and EPA's final additions to this list are:

- Biochemical oxygen demand (BOD) BOD is a pollution parameter which is often used as an indicator of the amount of organic chemicals present in the water sample. It is a standard laboratory test used to determine waste loadings to wastewater treatment plants and evaluate the efficiency of treatment systems.

- Total suspended solids (TSS) is a second laboratory measure of the organic and inorganic particulate matter present in wastewater.

- Fecal coliform bacteria are "recognized universally as indicators of sanitary water quality,"[3] as they indicate the potential presence of pathogenic intestinal organisms.

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[3] 43 FR 32857, July 28, 1978 ("Designations and Proposed Additions to 'Conventional' Pollutants List").

- The pH test measures acidity and alkalinity; changes in pH can effect the toxicity and solubility of many chemical compounds, including metals and metallic salts.

- Oil and grease is defined by the measurement method which identifies many similar "oil" substances of petroleum, animal and vegetable origin, all of which are oxygen-demanding.

Two other pollutant parameters, phosphorus and chemical oxygen demand (COD) were proposed for addition to the list but deleted from the final rule.[4] The most recent attempt to amend the list of conventional pollutants was a petition by the American Iron and Steel Institute to add ammonia and sulfide to the list. The petition was denied by EPA on December 1, 1980 [45 FR 79694] on the grounds that, while both substances are oxygen-demanding, naturally occurring and biodegradable, they have not traditionally been the primary focus of wastewater control, and thus did not meet one of the necessary criteria.

A review of the nine proposed regulations indicates that the major factor on which the agency relied in selecting BCT was that of "cost reasonableness" as calculated by the "BCT test" promulgated in August, 1979.[5] The BCT test compares the cost for a given technology to remove a pound of conventional pollutants to the cost incurred by a POTW for removing a pound of the same substance. If the POTW cost is higher, then the technology is considered to have passed the BCT test, i.e., to incur a "reasonable" cost.

The major advantage to the BCT regulations, according to EPA,[6] is that they establish a uniform measure of reasonableness for all industries throughout the county, and allocate a greater proportion of the total costs for control of conventional pollutants to the industries which face the lowest marginal cost.

In none of the regulations is any reference made to the health effects of various levels of control, only to whether the technology fits the requirements set forth in the CWA.

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[4] 44 FR 44501, July 30, 1979 ("Identification of Conventional Pollutants", Final Rule). COD was deleted because not all the substances measured by the test deplete oxygen which would otherwise be available for organisms. Phosphorus was deleted because it presents an environmental problem in only limited geographical areas, and thus did not justify the setting of a national standard.

[5] 44 FR 50732 (August 29, 1979).

[6] 44 FR 50733.

EFFLUENT LIMITATIONS FOR TOXIC POLLUTANTS

The 1977 Amendments shifted the focus of EPA's water pollution control strategy to the eventual elimination of all discharges and, in particular, discharges of toxic pollutants. To achieve this goal, the Agency is relying on the installation of BAT in regulated industries as required by Sections 301(b)(2)(C) through (F).

The pollutants are the 129 specific substances listed in Exhibit 2-5, selected by EPA from the list of 65 priority pollutants and classes of pollutants. Wastewater samples are analyzed for the presence of these substances at identifiable and measurable concentrations.

Having identified the specific pollutants discharged by the industry in question, EPA must select an effluent limitation which reflects BAT for that industry (or industry sub-category). According to EPA, its assessment "considers" costs, but does not require a balancing of costs against effluent reduction benefits [7]. In developing the proposed BAT, however, EPA has given substantial weight to the reasonableness of costs. The Agency has considered the volume and nature of discharges, the volume and nature of discharges expected after application of BAT, the general environmental effects of the pollutants, and the costs and economic impacts of the required pollution control levels.[8]

The reasons for selecting a technology as BAT for a particular industry vary among the proposed regulations, but all refer to the "cost reasonableness" criterion; e.g., "provides significant removal of the toxic pollutants of concern in this industry";[9] "provides substantial reductions of toxic pollutants (and costs are reasonable)";[10] "best supported by available data and affords further reduction in total pollutant discharges through the use of proven technology;"[11] or can "completely eliminate the discharge of toxic pollutants. . . without creating unacceptable economic or nonwater quality impacts."[12]

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[7] See Weyerhauser v. Costle, 11 ERC 2149 (D.D.C. 1978)

[8] These same factors are listed in the Preambles to all nine proposed regulations. See, e.g., 44 FR 38754 (Proposed regulations for leather tanning facilities).

[9] 44 FR 38755, July 2, 1979 (Proposed regulations for leather tanning and finishing facilities).

[10] 44 FR 62214, October 29, 1979 (Proposed regulations for textile mills)

[11] 44 FR 75934, December 21, 1979 (Proposed regulations for petroleum refineries).

[12] 45 FR 933, January 3, 1980 (Proposed regulations for ink formulating facilities).

EXHIBIT 2-5

TOXIC POLLUTANTS SELECTED FOR STUDY AND REGULATION UNDER TOXIC EFFLUENT GUIDELINES

acenaphthene
acrolein
acrylonitrile
1.2.4-trichlorobenzene
1.2-dichloroethane
hexachloroethane
1.1-dichloroethane
1.1.2-trichloroethane
chloroethane
bis (chloroethyl) ether
bis (2-chloroethyl) ether
2-chloroethly vinly ether
2-chloronaphthalene
para-chloro-meta-cresol
2-chlorophenol
1.3-dichlorobenzene
1.1-dichloroethylene
1.2-dichloropropane
1.3-dichloropropene (*cis-* & *trans*)
2.4-dimethylphenol
2.4-dinitrotoluene
2.6-dinitrotoluene
4-chlorophenyl phenyl ether
4-bromophenyl phenyl ether
bis-(2-chloroisopropyl) ether
bis-(2-chloroethoxy) methane
methyl chloride (chloromethane)
methyl bromide (bromomethane)
bromoform (tribromomethane)
bromodichloromethane
trichlorofluoromethane
dichlorodifluoromethane
dibromochloromethane
hexachlorobutadiene
hexachlorocyclopentadiene
2-nitrophenol
4-nitrophenol
2.4-dinitrophenol
4.6-dinitro-*o*-cresol
n-nitroso-dimethylamine
n-nitroso-di-*n*-propylamine
butyl benzyl phthalate
di-n/octyl phthalate

dimethyl phthalate
1.2-benzanthracene (benzo(a)anthracene)
3.4-benzopyrene (benzo(b)pyrene)
3.4-benzofluoranthene (benzo(b)fluoranthene)
11.12-benzofluoranthene
  (benzo(k)fluoranthene)
acenaphthylene
1.12-benzoperylene (benzo(ghi)perylene)
1.2.5.6-dibenzanthracene
  (dibenzo(a.h)anthracene)
indeno (1.2.3-cd) pyrene (1.2-o-phenylene
  pyrene)
trichloroethylene
vinyl chloride (chloroethylene)
aldrin
dieldrin
chlordane
4.4'-DDT
4.4'-DDE (p.p'-DDX)
4.4'-DDD (p.p'-TDE)
a-endosulfan
b-endosulfan
endosulfan sulfate
endrin
endrin aldehyde
heptachlor
heptachlor epoxide

a-BHC
b-BHC
r-BHC (lindane)
d-BHC
PCB-1242 (Arochlor 1242)
PCB-1254 (Arochlor 1254)
PCB-1221 (Arochlor 1221)
PCB-1232 (Arochlor 1232)
PCB-1248 (Arochlor 1248)
PCB-1260 (Arochlor 1260)
PCB-1016 (Arochlor 1016)
toxaphene
2.3.7.8-tetrachlorodibenzo-p-dioxin (TCDD)

trans-1.2-dichloroethene
1.1.1-trichloroethane
tetrachloromethane (carbon tetrachloride)
1.1.2.2-tetrachloroethene
1.1.2.2-tetrachloroethane
chlorobenzene
hexachlorobenzene
n-nitrosodiphenylamine
1.2-diphenylhydrazine
benzidine
3.3'-dichlorobenzidine
nitrobenzene
isophorone
fluorene
fluoranthene
pyrene
diethyl phthalate
di-*n*-butyl phthalate
chrysene
2.4-dichlorophenol

2.4.6-trihchlorophenol
chloroform
1.2-dichlorobenzene
1.4-dichlorobenzene
ethylbenzene
methylene chloride (dichloromethane)
naphthalene
petachlorophenol
phenol
bis (2-ethylhexyl) phthalate
toluene

chromium
copper
cyanide
lead
nickel
zinc

arsenic
selenium
silver
thallium

benzene
phenanthrene/anthracene
beryllium
cadmium
mercury
antimony
asbestos

The selection of BAT is considerably more discretionary than is the designation of BCT, which relies on a well-defined and fairly unambiguous cost comparison "test." To determine BAT, EPA must simply review the technological options and develop a justification of its final choice (strong enough to withstand legal challenge) as fulfilling the broad statutory requirements of Section 301(b)(2).

NEW SOURCE PERFORMANCE STANDARDS (NSPS)

Section 306 defines two requirements for establishing "national standards of performance" for new sources[13] in a specified list of industries (see Exhibit 2-6). The basis for new source performance standards (NSPS) under Section 306 of the Act is the best available demonstrated technology. According to EPA, new plants have the opportunity to design the best and most efficient. . . processes and wastewater treatment technologies, and therefore, Congress directed the Agency to consider the best demonstrated process changes, in-plant controls, and end-of-pipe treatment technologies which reduce pollution to the maximum extent feasible.

NSPS requires technologies which reduce effluents to the maximum extent feasible, and EPA appears to have defined feasible as taking costs and other factors into consideration. A review of the proposed regulations indicates that certain technologies were rejected because they were "too expensive and sophisticated for use in this industry";[14] did not "address the removal of toxic metal pollutants" or "because of the lower removal rate and higher cost compared to another option",[15] or because of "practical considerations and high costs".[16]

Where feasible, NSPS are to be set at zero discharge, taking into account possible non-water quality impacts of such standards (i.e., zero discharge into bodies of water may result in an increase in sludge production, which EPA might consider unacceptable). Of the nine proposed standards three (timber and ink and paint formulating) have recommended zero discharge as NSPS.

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[13] New source is defined as "any source, the construction of which is commenced after the publication of proposed regulations prescribing a standard of performance under this section which will be applicable to such source, if such standard is thereafter promulgated in accordance with this section." See 40 CFR 403.3(j).

[14] 44 FR 38756, July 2, 1979 (Proposed regulations for leather tanning and finishing facilities).

[15] 44 FR 68717, November 29, 1979 (Proposed regulations for gum and wood chemical manufacturers).

[16] 45 FR 68336, October 14, 1980 (Proposed regulations for steam electric power plants).

EXHIBIT 2-6

CATEGORIES OF SOURCES REQUIRING NSPS

pulp and paper mills
paperboard, builders paper and board mills
meat product and rendering processing
dairy product processing
grain mills
canned and preserved fruits and vegetables processing
sugar processing
textile mills
cement manufacturing
feedlots
electroplating
organic chemicals manufacturing
inorganic chemicals manufacturing
plastic and synthetic materials manufacturing
soap and detergent manufacturing
fertilizer manufacturing
petroleum refining
iron and steel manufacturing
nonferrous metals manufacturing
phosphate manufacturing
steam electric powerplants
ferroalloy manufacturing
leather tanning and finishing
glass and asbestos manufacturing
rubber processing
timber products processing

PRETREATMENT STANDARDS FOR EXISTING AND NEW INDIRECT DISCHARGERS

Sections 307 (b) and (c) require EPA to promulgate pretreatment standards for both existing and new sources which are indirect dischargers (i.e., sources whose wastewater is treated by a POTW). In either case, the following pollutants are prohibited from being introduced into a POTW:

(1) Pollutants which create fire and explosion hazards in the POTW;

(2) Pollutants which will cause corrosive structural damage to the POTW, but in no case discharges with pH lower than 5.0, unless the works is specifically designed to accommodate such discharges;

(3) Solid or viscous pollutants in amounts which will cause obstruction to the flow in sewers, or other interference with the operation of the POTW;

(4) Any pollutant, including oxygen demanding pollutants (BOD, etc.), released in a discharge of such volume or strength as to cause interference in the POTW.

(5) Heat in amounts which will inhibit biological activity in the POTW resulting in interference but in no case heat in such quantities that the temperature at the treatment works influent exceeds 40°C (104°F) unless the works is designed to accomodate such heat. [40 CFR Part 403.6]

Pretreatment standards for both existing sources (PSES) and new sources (PSNS) were designed "to prevent the discharge of pollutants that pass through, interfere with, or are otherwise incompatible with the operation of POTWs."[17] The 1977 Amendments additionally require pretreatment for pollutants such as heavy metals, which might limit POTW sludge management alternatives. Of concern here appears to be potential beneficial uses of sludge, e.g., as fertilizer for agricultural lands. Pollutants which would make the sludges from POTWs unfit for such beneficial uses are to be controlled at the source.

As interpreted by EPA, the legislative history of the 1977 Act indicated that pretreatment standards were to be technology-based and analogous to the best available technology for removal of toxic pollutants.[18] As with the other guidelines and standards, the methodology used to set PSES (and PSNS) was to identify several technological options and to select the one which seemed best to fit the specified criteria. The justifications for particular choices referred less to the cost factor than did either the BCT or BAT regulations, although consideration of extreme costs was a factor in rejecting certain options. The following excerpts from the Preambles to some of the proposed regulations provide an indication of the types of decision criteria employed:

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[17] Sections 307(b) and (c).

[18] This interpretation is included in the Preambles to each of the proposed regulations. See, e.g., 44 FR 38746 (Proposed regulations for leather tanning facilities).

- [This option] ensures the removal of approximately 36% of the organic and 55% of the metal toxic pollutants and allows POTWs more flexibility in sludge disposal. [A second option] was rejected because it provides no control of toxic pollutants or protection against the contamination of POTW sludge.[19]

- [The option selected provides] complete elimination of discharges of pollutants as the basis for PSES . . . Not only will this option prevent the discharge of high concentrations of toxic solvents to POTWs, but solvents also have an economic value and can either be sold to scavengers or reclaimed on-site and re-used.[20]

- [The option chosen] will insure removal of the bulk of trivalent chromium and other heavy metals at the industrial site and give POTWs more flexibility in sludge disposal. [Another option was rejected] primarily because the projected economic impact was high and because space and land constraints of existing plants would not permit widespread installation of these technologies.[21]

Such comments are representative of the arguments made in support of a selected technological option and suggest that cost reasonableness is less of a factor in setting pretreatment standards for existing sources than for setting either BAT or BCT.

Pretreatment standards for new sources (PSNS), required under Section 307(c), are to be promulgated concurrently with NSPS. EPA's strategy toward regulating new indirect discharges has been to require such sources to meet the most stringent of standards, with the justification that:

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[19] 44 FR 62204, October 29, 1979 (Proposed regulations for gum and wood chemicals).

[20] 45 FR 928, January 3, 1980 (Proposed regulations for ink formulating).

[21] 44 FR 38746, July 7, 1979 (Proposed regulations for leather tanning and finishing facilities).

> New indirect dischargers, like new direct dischargers, have the opportunity to incorporate the best available demonstrated technologies including process changes, in-plant control measures, and end-of-pipe treatment, and to use plant site selection to ensure adequate treatment system installation.[22]

In other words, PSNS are to be the technological equivalent, for indirect dischargers, of NSPS for direct dischargers.

As was the case with PSES, the explanations of the PSNS selection process indicate that cost, while a factor, was not the overriding consideration in making a determination:

> - [This option was selected] because it ensures the removal of approximately 60% of the significant organic and 50% of the significant metallic toxic pollutants and allows POTWs more flexibility in sludge disposal. In addition, the technology further increases protection against the discharge of high levels of COD and color. . . .[23]
>
> - [Zero discharge was selected because] the Agency's economic impact analysis. . . concluded that the cost of designing and installing the proper systems needed to achieve the no discharge status would not hinder the addition of new capacity.[24]
>
> - [PSNS was set equal to PSES because this option] will provide the removal of the [bulk of] heavy metals at the source for greater efficiency of removal at less cost.[25]

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[22] This justification is presented in each of the Preambles to the proposed regulations. See, e.g., 44 FR 38746 (Proposed regulations for leather tanning and finishing facilities).

[23] 44 FR 62204, October 29, 1979 (Proposed regulations for textile mills).

[24] 44 FR 62810, October 31, 1979 (Proposed regulations for timber processors).

[25] FR 68710, November 29, 1979 (Proposed regulations for gum and wood chemicals).

EPA's strategy seems to have been to consider first the level of control provided by each of the options, and only to consider costs where they appear to be extreme or unwarranted.

Although a justification has been made by EPA for expecting more stringent controls of new sources, five of the nine proposed standards have set PSES equal to PSNS. Of these, two (paint and ink formulating) set both at zero discharge. Of the four which propose differential standards, PSNS is the more stringent of the two and, for timber processing plants, is set at zero discharge as well.

TOXIC POLLUTANT EFFLUENT STANDARDS--REGULATORY REVIEW

This section reviews the Toxic Pollutant Effluent Standards, 40 CFR 129, promulgated under Section 307 of the Clean Water Act (or CWA), including:

(1) the criteria used by EPA to list chemical substances as toxic pollutants under Section 307;

(2) the chemical substances designated as toxic pollutants;

(3) the criteria used by EPA to establish effluent standards; and

(4) the types of effluent standards developed for toxic pollutants.

Exhibit 2-7, Regulatory Chronology, summarizes the regulatory actions reviewed.

NINE TOXIC POLLUTANTS: DESIGNATION AND PROPOSED EFFLUENT STANDARDS

The 1973 Amendments to the Clean Water Act instructed EPA to publish "a list which includes any toxic pollutant[1] or combination of such pollutants for which an effluent standard . . . will be established. . ." (Section 307(a)(1)). To list pollutants as toxic, EPA must consider:

- the toxicity, persistence and degradability of the pollutant,
- the usual or potential presence of the affected organisms in any waters (i.e., are affected organisms found or in the future will they be found in waters where discharges may occur?),
- the importance of the affected organisms, and

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[1] The term, "toxic pollutant" is defined in Section 502(13) of the Act as "those pollutants or combinations of pollutants, including disease causing agents, which after discharge and upon exposure, ingestion, inhalation or assimilation into any organism, either directly from the environment or indirectly by ingestion through food chains will, on the basis of information available to the Administrator, cause death, disease, behavioral abnormalities, cancer, genetic mutations, physiological malfunctions (including malfunctions in reproduction) or physical deformations in such organisms or their offspring."

EXHIBIT 2-7

SECTION 307 OF THE CLEAN WATER ACT: REGULATORY CHRONOLOGY

DATE	EPA REGULATORY ACTION	FEDERAL REGISTER CITATION
September 7, 1973	Published List of Nine Toxic Pollutants	38 FR 24342
October 26, 1973	Proposed Water Quality Criteria Documents	38 FR 29646
December 27, 1973	Proposed Effluent Standards for Nine Listed Toxic Pollutants	38 FR 35388
April, May 1974	Evidentiary Hearing on Proposed Effluent Standards	-----------
June 10, 1976	Proposed Revised Effluent Standards for Aldrin/Dieldrin, DDT, Endrin, and Toxaphene	41 FR 23576
June 30, 1976	Proposed Revised Effluent Standards for Benzidine	41 FR 27012
July 23, 1976	Proposed Revised Effluent Standards for PCBs	41 FR 30468
January 12, 1977	Promulgated Effluent Standards for Aldrin/Dieldrin, DDT, Endrin, Toxaphene, and Benzidine	42 FR 2588, 2617
February 2, 1977	Promulgated Effluent Standards for PCBs	42 FR 6532
January 31, 1978	Published List of 65 Toxic Pollutants	43 FR 4108
March 15, 1979	(1) Published Water Quality Criteria for 65 Toxic Pollutants (2) Published Guidelines for Deriving Water Quality Criteria.	44 FR 15930 44 FR 15926
March 27, 1979	Issued Guidance on Revisions of Toxic Pollutant List	44 FR 18279
July 30, 1979	Amended General Provisions for Effluent Guidelines and Standards, 40 CFR 401.15 to Include List of 65 Toxic Pollutants	44 FR 44502

EXHIBIT 2-7 (continued)

SECTION 307 OF THE CLEAN WATER ACT: REGULATORY CHRONOLOGY

DATE	EPA REGULATORY ACTION	FEDERAL REGISTER CITATION
October 17, 1979	Denied Dow Chemical Company's Petition to Remove Aromatic Haloethers from the Toxic Pollutant List	45 FR 59948
January 3, 1980	Proposed Addition of Ammonia to Toxic Pollutant List	45 FR 803
April 7, 1980	Denied Dow Chemical Company's Petition to Remove 1,1,1-Trichloroethane and Methylene Chloride from the Toxic Pollutant List	45 FR 23512
July 9, 1980	Proposed Removal of F-11 and F-12 from the Toxic Pollutant List	45 FR 46103
September 15, 1980	Proposed Removal of Bis-(chloromethyl) Ether (BCME) from the Toxic Pollutant List	45 FR 60942
November 28, 1980	New water quality critiera for 64 toxic pollutants	45 FR 79318
December 1, 1980	Withdrew Proposal to Add Ammonia to Toxic Pollutant List	45 FR 79692
January 8, 1981	(1) Removed F-11 and F-12 From the Toxic Pollutant List	46 FR 2266
	(2) Denied Dow Chemical Company's Petition to Remove Phenol, 2,4-Dichlorophenol, 2,4,5-Trichlorophenol, Pentachlorophenol, and Ethylbenzene from the Toxic Pollutant List	46 FR 2267
	(3) Proposed Denial of Dow's Petition to Remove Monochlorophenyl Phenyl Ether (CIDPO) from The Toxic Pollutant List	46 FR 2273

- the nature and extent of the effect of the toxic pollutant on such organisms.[2]

EPA designated nine pollutants as toxic substances on September 7, 1973 because they met the following criteria:[3]

(1) Data from laboratory or field studies indicated that the pollutant could, if discharged into water, constitute a serious environmental threat.

(2) The pollutant was discharged, or had the potential to be discharged, from point sources and constituted a very serious environmental threat.

(3) Data were available to establish effluent standards which met the requirements of the Act.

(4) Standard setting under Section 307(a) was "appropriate," and was "necessary."

Exhibit 2-8 presents a detailed explanation of these criteria. Exhibit 2-9 lists the nine designated toxic pollutants and identifies the types of effects which led EPA to conclude that each chemical posed a serious environmental threat (i.e., met the requirements of Criterion (1) above).

On December 27, 1973, EPA proposed effluent standards for each of the nine listed toxic pollutants (38 FR 35388). EPA identified the following four factors as instrumental in setting the standards:

(1) toxicological data,

(2) hydrodynamic data,

(3) ample margins of safety, and

(4) calculations of acute and chronic toxicity levels.

The primary sources for toxicological and hydrodynamic data were Water Quality Criteria Documents proposed in October 1973. Because there was no proposed water quality criteria document for benzidine from which toxicological and

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[2] Section 307(a)(1) of the Clean Water Act.

[3] Preamble to the List of Toxic Pollutants, 38 FR 24342, September 7, 1973.

EXHIBIT 2-8

DESIGNATION CRITERIA FOR THE NINE TOXIC POLLUTANTS (1973)[a/]

Criterion (1): Toxicological Effects Used to Indicate an Environmental Threat

(A) Bioaccumulation: Data was reviewed to determine if a substance or its chemical or biological transformation product was bioaccumulated through an aquatic mechanism and resulted in reproductive impairment in any important species or resulted in concentrations in food sources in excess of applicable Federally established tolerance levels.

(B) Carcinogenic, Mutagenic and Teratogenic Effects: Chemicals likely to have these effects in humans were evaluated for chemical, biological, and physical stability in water.

(C) High Acute Toxicity:

(1) Chemicals classified as "highly toxic" by the Environmental Protection Agency under the Federal Insecticide, Fungicide, and Rodenticide Act (40 CFR 162.8) and by the Food and Drug Administration testing procedures (21 CFR 191.10) were considered for designation.

(2) Substances proposed to be classified as "highly toxic" according to the National Academy of Sciences water pollution ranking system also were considered for inclusion in the list.

Criterion (2): Factors to Assess the Seriousness of Discharges

Seriousness of discharges data included such characteristics of the pollutant as:

(A) the nature and extent of toxic effects,

(B) the extent to which discharges have been identified, and

(C) the production, distribution, and use pattern.

EPA specified that seriousness of discharges data must be from "well documented field studies showing damage to important organisms from discharges of the compound into waters, or technically sufficient to show the material has the potential to be environmentally harmful after being discharged from point sources to the water." (38 FR 24342)

EXHIBIT 2-8 (continued)

DESIGNATION CRITERIA FOR THE NINE TOXIC POLLUTANTS (1973)[a/]

Criterion (3): Types of Data Necessary to Establish Effluent Standards Under the Clean Water Act

The following were identified by EPA as representative of the categories of data useful in standard setting:

(A) Toxicity to man and other organisms;

(B) Carcinogenicity, mutagenicity, and teratogenicity data;

(C) Transport paths of the material in the environment;

(D) Bioaccumulation and bioconcentration;

(E) Chemical, physical, and biological transformations in the environment;

(F) Reliability and accuracy of analytical procedures;

(G) Chemical characteristics;

(H) Production and industrial or commercial utilization;

(I) Sources of pollutant discharges to water;

(J) Environmental incidents attributable to the material (fish kills, etc.);

(K) Presence of the material in the environment, residue levels in various organisms, ambient concentrations in rivers, lakes, etc.;

(L) State and Federal regulatory requirements concerning the material;

(M) Classes and characteristics of waters into which the material is discharged.

EXHIBIT 2-8 (continued)

DESIGNATION CRITERIA FOR THE NINE TOXIC POLLUTANTS (1973)[a]

Criterion (4): Environmental Effects of Available Control Measures

EPA evaluated the prospective timing and effectiveness of abatement actions under other provisions of the Act to ensure that other control measures were not commensurate with the nature and seriousness of the problems identified by the above criteria. In addition, the Agency considered the environmental effects of substitute products and the possible effects of pollutants on ground water and other environmental media. In this way, EPA determined that regulation of the nine pollutants under Section 307(a) was "appropriate" and "necessary."

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[a] Preamble to the List of Toxic Pollutants, 38 FR 24342, September 7, 1973.

EXHIBIT 2-9

NINE DESIGNATED TOXIC POLLUTANTS AND THEIR TOXICOLOGICAL EFFECTS

List of Toxic Pollutants	High Order of Toxicity to Aquatic Organisms	High Order of Toxicity To Humans	Carcinogenicity	Bioaccumulation
(1) Aldrin[a] (1,2,3,4,10,10-hexachloro-1,4,4a,5,8,8a-hexahydro-1,4,5,8, endo-exodi-methano-naphthalene) Dieldrin (1,2,3,4,10,10-hexachloro-6,7-epoxy-1,4,4a,5,6,7,8,8a-octahydro-1,4-endo,exo-5,8-dimethano-naphthalene).	X			X
(2) Benzidine and its salts (para-para'-di-aminobiphenyl).			X	
(3) Cadmium and all cadmium compounds	X			X
(4) Cyanide and all cyanide compounds	X			
(5) DDD (TDE)1,1-dichloro-2,2-bis (para-chlorophenyl)-ethane DDE(dichlorodiphenyldichloroethylene) 1,1-dichloro -2,2- bis (para-chlorophenyl) ethylene DDT (dichlorodiphenyltrichloroethane) 1,1,1-trichloro-2,2-bis (para-chlorophenyl) ethane	X			X
(6) Endrin (1,2,3,4,10,10-hexachloro-6,7-epoxy-1,4,4a,5,6,7,8,8a-octahydro-1,4-endo-5,8-endo-dimethano-naphthalene).	X			
(7) Mercury and All Mercury Compounds				X
(8) Polychlorinated biphenyls (PCBs)	X	X		X
(9) Toxaphene (chlorinated camphene)	X	X		

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[a] Aldrin and Dieldrin were designated as a single entity because aldrin is rapidly transformed to dieldrin in the environment.

hydrodynamic data could be examined, EPA derived effluent standards for benzidine by extrapolating laboratory animal data to humans.[4]

To provide an ample margin of safety for acute toxic effects, EPA chose a concentration limit of one tenth the 96-hour LC50 for each chemical.[5] EPA presented no rationale for selecting the particular one tenth factor.

To protect against chronic toxicity, EPA limited the total weight of a pollutant which could be discharged into receiving waters of a given size. To provide an ample margin of safety, EPA reduced the allowable weight of a chemical discharged per unit of water flow by safety factors. These safety factors were designed to compensate for non-point sources of the pollutant, multiple discharges in a small area, industrial growth, and the difference in water storage times among lakes, estuaries, streams, and coastal waters.[6]

The 1973 proposed standards were developed under time constraints imposed by a court order in response to litigation commenced by the Natural Resources Defense Council (NRDC v. Fri, Civ. Action No. 849-73 (D.D.C. June 19, 1973, as modified)). As a result, EPA did not have sufficient time to develop data in certain areas. A thirty-day evidentiary hearing was held on the proposed standards in April and May 1974 where industry representatives introduced evidence of data gaps in EPA's standard setting process concerning:

(1) analytical and monitoring technology,

(2) hydrological assumptions,

(3) availability of control technology,

(4) economic impacts, and

(5) identity of point source discharges.

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[4] Water Quality Criteria Documents were proposed by EPA on October 26, 1973 (38 FR 29646) pursuant to Section 304(a) of the Clean Water Act. Water Quality Criteria Documents are not to be confused with the Drinking Water Quality Criteria which are separate documents.

[5] The 96-hour LC50 is that concentration derived from laboratory tests in which 50 percent of a group of test organisms survive after 96 hours of continuous exposure to a pollutant. The 96-hour LC50 is a common acute toxicity test.

[6] Proposed Toxic Pollutant Effluent Standards, 38 FR 35388, December 27, 1973.

EPA concluded that the data gaps in the hearing record meant that EPA could not fully substantiate the proposed standards at that time. As a result, the Agency decided to gather additional information and repropose new standards at a later date.[7]

SIX TOXIC POLLUTANTS: 1976 REPROPOSED EFFLUENT STANDARDS

EPA reproposed effluent standards in 1976 for the following six chemicals which were among the nine toxic pollutants for which standards were initially proposed in 1973:

(1) Aldrin/Dieldrin[8]

(2) DDT

(3) Endrin

(4) Toxaphene

(5) Benzidine

(6) Polychlorinated Biphenyls (PCBs)

Subsequently, Toxic Pollutant Effluent Standards, 40 CFR 129 were promulgated by EPA for these six chemicals.[9] Exhibit 2-10 displays the six toxic pollutants and their definitions as they appear in Part 129.4 of the regulations.

EPA did not repropose effluent standards for all nine toxic pollutants because the Agency decided that concurrent action on a more limited number of standards would result in higher quality rulemakings in each case. According to EPA, to propose and promulgate nine effluent standards simultaneously posed "unwarranted and intolerable burdens" on the objecting parties and the Agency

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[7] Preamble to Proposed Toxic Pollutant Effluent Standards, 41 FR 23577, June 10, 1976.

[8] Aldrin and Dieldrin are regulated as a single entity because aldrin is rapidly transformed to dieldrin in the environment.

[9] Effluent standards for Aldrin/Dieldrin, DDT, Endrin, Toxaphene, and Benzidine were promulgated on January 12, 1977 (42 FR 2588,2617). PCB's effluent standards were promulgated on February 2, 1977 (42 FR 6532). The six effluent standards are applicable to classes or categories of point sources only if the standards "impose more stringent requirements" on the point sources than the (BAT) effluent limitations promulgated under Sections 301(b)(2) and 304(b)(2) of the CWA.

EXHIBIT 2-10

SIX 1976 TOXIC POLLUTANTS AND THEIR DEFINITIONS

(1) Aldrin/Dieldrin: "'Aldrin' means the compound aldrin as identified by the chemical name, 1,2,3,4,10,10-hexachloro-1,4,4a,5,8,8a-hexahydro-1,4-endo-5,8-exo-dimethanonaphthalene."

"Dieldrin means the compound dieldrin as identified by the chemical name 1,2,3,4,10,10-hexachloro-6,7-epoxy-1,4,4a,5,6,7,8,8a-octahydro-1,4,-endo-5,8-exo-dimethanonaphthalene."

(2) DDT: "'DDT' means the compounds DDT, DDD, and DDE as identified by the chemical names: (DDT)-1,1,1-trichloro-2,2-bis (p-chlorophenyl) ethane and some o, p'-isomers; (DDD) or (TDE)-1,1-dichloro-2,2-bis (p-chlorophenyl) ethane and some o, p'-isomers; (DDE)-1,1-dichloro-2,2-bis (p-chlorophenyl) ethylene."

(3) Endrin: "'Endrin' means the compound endrin as identified by the chemical name 1,2,3,4,10,10-hexachloro-6,7-epoxy-1,4,4a,5,6,7,8,8a-Octahydrol,4-endo-5,8-endo-dimethanonaphthalene."

(4) Toxaphene: "'Toxaphene' means a material consisting of technical grade chlorinated camphene having the approximate formula of $C_{10}H_{10}C_{18}$ and normally containing 67-69 percent chlorine by weight."

(5) Benzidine: "'Benzidine" means the compound benzidine and its salts as identified by the chemical name 4,4'-di-aminobiphenyl."

(6) Polychlorinated Biphenyls (PCBs): "Polychlorinated biphenyls (PCBs) means a mixture of compounds composed of the biphenyl molecule which has been chlorinated to varying degrees."

Source: 40 CFR 129.

(41 FR 23579). Instead, EPA proposed and promulgated "responsible and defensible standards for the six chemicals with adequate data bases."[10]

Statutory Criteria for Designation and Standards

At the time the six effluent standards were promulgated, Section 307(a)(2) of the Act (as amended in 1972) required EPA to consider "the toxicity of the pollutant, its persistence, degradability, the usual or potential presence of the affected organisms in any waters, the importance of the affected organisms and the nature and extent of the effect of the toxic pollutant on such organisms, and the extent to which effective control is being or may be achieved under other regulatory authority." (Section 307(a)(2) as amended in 1972). Furthermore, Section 307(a)(4) of the Act directed EPA to establish effluent standards at a level which provided "an ample margin of safety." To derive such a level, EPA first reviewed the toxicity considerations enumerated in Section 307(a)(2) (described above). EPA regarded these toxicity considerations as "the most important elements in setting the standards."[11]

Toxicity information for the six pollutants was assembled in water quality criteria documents published by EPA. The criteria documents presented data derived from laboratory studies and field observations on a variety of organisms including invertebrate, vertebrate and mammalian test species. Investigations conducted by EPA's Office of Research and Development provided acute and chronic toxicity data concerning the feeding of aquatic organisms and consumers of aquatic organisms. Furthermore, bioaccumulation studies, human toxicity data, mammalian carcinogenesis studies, persistence information, and degradability data were used to evaluate toxic effects of pollutants. Since data were not available on all species, EPA relied on a wide range of toxicity data for a phylogenetic cross section of organisms as well as species representative of a wide geographic distribution.[12]

The "importance" of organisms likely to be affected by the effluent standards was evaluated as required by Section 307(a). EPA assessed the ecological importance of an organism by examining

(1) the role the organism played within the ecosystem,

(2) the relationship of the organism to the food chain within the aquatic community, and

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[10] Proposed Toxic Pollutant Effluent Standard for PCBs, 41 FR 30468, July 23, 1976.

[11] 41 FR 23579, June 10, 1976.

[12] Ibid.

(3) the connection of the organism to consumers of aquatic life, including humans.

To assess human health effects, EPA generally relied on extrapolations from animal data, although in some cases clinical and epidemiological studies were available. Determinations of a chemical's carcinogenicity were made following the principle that any substance shown to cause tumors in animals was considered a suspect human carcinogen.[13]

Human beings were not specifically identified in Section 307 as organisms to be protected by effluent limitations but EPA interpreted the statute to require the protection of human health in addition to aquatic life. In support of its position, the Agency referred to Section 402(k) of the Clean Water Act which describes standards imposed under Section 307 as intended for "toxic pollutant(s) injurious to human health." In addition, the definition of "toxic pollutant" in Section 502(13) mentions health effects in humans as well as in aquatic organisms. EPA cited a report of the Senate Committee on Public Works which describes the definition of "toxic pollutant" referred to above as "a benchmark for evaluating those pollutants which in certain concentrations would have a particularly adverse impact on humans as well as other forms of life."[14] This report also suggested that EPA consider in promulgating standards "the seriousness and irreversibility of any effects on man or the environment that might occur" and "the possibility for incorporation into biological organisms and man in concentrations which the latest scientific knowledge suggests will produce effects on man and organisms."[15] For these reasons, EPA promulgated 40 CFR 129.5(c)(2) which states ". . . all toxic pollutants for which standards are set under this Part are deemed to be injurious to human health within the meaning of Section 402(k) of the Act unless otherwise specified. . .".

Recommended Maximum Ambient Levels

In addition to toxicity data and human health effects information, EPA used the recommended maximum ambient level for each pollutant as a guide to establish regulatory requirements. The recommended maximum ambient levels were published by EPA in the criteria documents to provide "an ample margin of safety" for aquatic organisms and others up the food chain, including humans, who may be exposed to it.[16] The recommended ambient level was referred to as the ambient water criterion and was expressed in micrograms per liter (ug/l) or the equivalent measurement of parts per billion (ppb). Ambient water criteria were based solely on data and scientific judgment, and did not reflect considerations of economic or technological feasibility.

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[13] Water Quality Criteria, 44 FR 15930, March 15, 1979.

[14] S. Rept. No. 92-414, 92nd Cong, 1st Session, October 28, 1971, p. 77. Also "A Legislative History of the Water Pollution Control Act Amendments of 1972," p. 1495.

[15] "Legislative History," p. 1496.

[16] 41 FR 23579, June 10, 1976.

Deriving Effluent Limitations from Ambient Water Criteria

The ambient water criterion numbers served as guides for establishing effluent limitations. However, translating a safe water quality criteria number into an end-of-the-pipe standard is at best an imprecise calculation.[17] Actual discharge concentrations do not normally remain ambient concentrations because pollutants are diluted and dispersed in the receiving water. For this reason effluent limitations established at the level of the ambient water criterion would be unnecessarily stringent to protect public health. Instead, EPA did the "very best that was possible within the bounds of feasibility" to set standards "which achieved or most nearly approached the ambient water criterion."[18]

Section 307 of the Clean Water Act (as amended in 1972) did not explicitly state that EPA must consider the technological or economic feasibility of effluent standards. Because the statute did not preclude consideration of these factors, EPA decided that "the interests of responsible rulemaking were best served by giving at least some consideration to technological factors and the likely impact, if any, of the proposed regulations on the national economy."[19] It is important to emphasize that EPA places "toxicity" and "ample margin of safety" ahead of "economically achievable" in writing regulations under Section 307(a).

EPA based this decision on implications from the language of Section 307. Section 307(a)(5) authorizes EPA to establish toxic standards at different levels for different categories of point sources. EPA assumed this meant that the different standards must be based on technological or economic differences in the control techniques because health and environmental effects provide no basis for distinguishing among point source categories. Furthermore, EPA referred to the language of Section 307(a)(1) and (2) which require that EPA take into account "the importance of the affected organisms" when listing and regulating toxic pollutants. EPA inferred from this language that the importance of affected organisms should be considered in relation to other important social and economic values, namely economic and technological feasibility, although technological and economic feasibility "must always be given less weight than environmental and public health factors."[20]

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[17] 41 FR 23580, June 10, 1976.

[18] Ibid.

[19] Preamble to Proposed Toxic Pollutant Effluent Standards, 41 FR 23578, June 10, 1976.

EPA set the six toxic pollutant effluent limitations at the point which represented "the very best that control technology could do" (41 FR 23580). EPA prohibited discharges of pollutants only if:[21]

(1) there were no known discharges in the category covered; or

(2) technology could feasibly achieve a prohibition.

In this way, EPA attempted to provide an "ample margin of safety" without inflicting unreasonable and unjustifiable economic and social costs (41 FR 23580).

Part 129.7 of the regulations gave EPA the authority to impose a more stringent effluent limitation on a particular source than required by the general effluent standards if:

(1) the ambient water criterion was not being met or would not be met in the receiving water, and

(2) the ambient water concentration "may cause or contribute to significant adverse effects on aquatic or other organisms usually or potentially present or on human health."[22]

This mechanism was included in the regulations to account for unusual receiving water conditions where general dispersion and dilution do not occur.

Summary: Effluent Standards Criteria

The criteria used by EPA to establish Toxic Pollutant Effluent Standards are summarized in Exhibit 2-11. In addition, the type of standard issued (i.e., prohibition or limitation of discharges) for each chemical is specified.

In all cases except for one, benzidine, EPA considered the non-carcinogenic toxic effects of the chemical on aquatic animals, mammals, and humans.

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[20] 41 FR 23578, June 10, 1976.

[21] Discharges of aldrin/dieldrin, DDT, and PCBs were prohibited by EPA.

[22] 40 CFR 129.7(a).

EXHIBIT 2-11

EFFLUENT STANDARDS CRITERIA FOR THE SIX TOXIC POLLUTANTS

Effluent Criteria	Aldrin/ Dieldrin	DDT	Endrin	Toxaphene	Benzidine	PCBs
1. Toxicity	x	x	x	x		x
(a) Aquatic Animals	x	x	x	x		x
(b) Mammals	x	x	x	x		x
(c) Humans	x	x	x	x		x
2. Carcinogenicity	x	x			x	x
(a) Laboratory Animal Data	x	x			x	x
(b) Low-dose risk extrapolation modeling ("one-hit" model)					x	
3. Persistence	x	x	x	x		x
4. Degradability	x	x	x	x		x
5. Bioaccumulation	x	x	x	x	x	x
6. Water Quality Criterion	x	x	x	x	x	x
7. Application Factor	x	x	x	x		
8. Feasibility	x	x	x	x	x	x
9. Substitutes						x
Type of Standard						
1. Prohibition	x	x				x
2. Limitation			x	x	x	

Benzidine was not studied extensively for non-carcinogenic toxicity since the main concern was its carcinogenic effects.

Four of the chemicals were regarded as carcinogens because laboratory animal experiments demonstrated carcinogenic effects. The effluent standard for one of these carcinogens, benzidine, was set by using low-dose extrapolation modeling. Specifically, the "one-hit" model estimated from laboratory animal data the concentration of benzidine which would result in carcinogenic effects in humans.

All of the chemicals except benzidine were found to be highly persistent in the environment and resistant to degradation. Benzidine had neither characteristic. Each chemical bioaccumulated and this factor was a primary consideration in setting the effluent standards.

Ambient Water Quality Criteria were instrumental in establishing effluent standards in each case. To derive chronically safe exposure levels from acute toxicity data, EPA multiplied an "application factor" times the demonstrated acute toxicity levels for aldrin/dieldrin, endrin, DDT, and toxaphene.[23]

After considering the available toxicological information and the ambient water criteria numbers, EPA set the effluent standards within the bounds of technological and economic feasibility. In the case of PCBs, substitutes for the chemicals were examined as part of EPA's determination that the PCB effluent prohibition was economically feasible.

TOXIC POLLUTANT LIST REVISED BY THE 1977 AMENDMENTS

EPA revised the toxic pollutant list in accordance with the 1977 Amendments to the Clean Water Act which directed the Agency to publish the list of toxic pollutants shown in Exhibit 2-12 (Section 307(a)(1)). This list of 65 toxic pollutants includes the six pollutants for which effluent standards were promulgated in 1977 and the nine pollutants for which effluent standards wereproposed in 1973. Furthermore, the Clean Water Act Amendments of 1977 require EPA to establish effluent limitations "for every toxic pollutant referred to" in the list (Section 307(a)(2)). Through January 1, 1981, no new effluent standards had been proposed or promulgated for the 65 toxic pollutants.

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[23] Application factors are not uniform among chemicals and are based on bioaccumulation potential. An application factor of 0.01 was derived for aldrin/dieldrin, endrin, DDT, and toxaphene by the National Academy of Sciences National Academy of Engineering and published in "Water Criteria 1972" (Washington, D.C., 1973). One application factor was derived for all four substances above because the substances share similar chemical structures and bioaccumulation properties.

EXHIBIT 2-12

TOXIC POLLUTANT LIST AS REVISED BY THE 1977 AMENDMENTS[a]

Acenaphthene
Acrolein
Acrylonitrile
Aldrin/Dieldrin[b],[c]
Antimony and compounds[d]
Arsenic and compounds
Asbestos
Benzene
Benzidine[b]
Beryllium and compounds
Cadmium and compounds
Carbon tetrachloride
Chlordane (technical mixture and metabolites)
Chlorinated benzenes (other than dichlorobenzenes)
Chlorinated ethanes (including 1,2-dichloroethane, 1,1,1-trichloroethane, and hexachloroethane)
Chloroalkyl ethers (chloromethyl, chloroethyl, and mixed ethers)
Chlorinated naphthalene
Chlorinated phenols (other than those listed elsewhere; includes trichlorophenols and chlorinated cresols)
Chloroform
2-chlorophenol
Chromium and compounds
Copper and compounds
Cyanides
DDT and metabolites[b]
Dichlorobenzenes (1,2-, 1,3-, and 1,4-dichlorobenzenes)
Dichlorobenzidine
Dichloroethylenes (1,1- and 1,2-dichloroethylenes
2,4-dichlorophenol
Dichloropropane and dichloropropene
2,4-dimethylphenol
Dinitrotoluene
Diphenylhydrazine
Endosulfan and metabolites
Endrin and metabolites[b]
Ethylbenzene

Fluoranthene
Haloethers (other than those listed elsewhere; includes chlorophenylphenyl ethers, bromophenylphenyl ether, bis(dischloroisopropyl), ether, bis-(chloroethoxy) methane and polychlorinated diphenyl ethers)
Halomethanes (other than those listed elsewhere; includes, methylene, chloride methylchloride, methylbromide, bromoform, dichlorobromomethane, trichlorofluoromethane, dichlorodifluoromethane)
Heptachlor and metabolites
Hexachlorobutadiene
Hexachlorocyclohexane (all isomers)
Hexachlorocyclopentadiene
Isophorone
Lead and compounds
Mercury and compounds
Naphthalene
Nickel and compounds
Nitrobenzene
Nitrophenols (Including 2,4-dinitrophenol dinitrocresol)
Nitrosamines
Pentachlorophenol
Phenol
Phthalate esters
Polychlorinated biphenyls (PCBs)[b]
Polynuclear aromatic hydrocarbons (including benzanthracenes, benzopyrenes, benzofluoranthene, chrysenes, dibenzanthracenes, and indenopyrenes)
Selenium and compounds
Silver and compounds
2,3,7,8- Tetrachlorodibenzo-p-dioxin (TCDD)
Tetrachloroethylene
Thallium and compounds
Toluene
Toxaphene[b]
Trichloroethylene
Vinyl chloride
Zinc and compounds

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[a] 40 CFR 401.15, 44 FR 44502, July 30, 1979.

[b] Effluent standard promulgated (40 CFR 129).

[c] Aldrin and dieldrin were listed as a single entity because aldrin is rapidly transformed to dieldrin in the environment. These substances are also regulated as a single entity.

[d] The term "compounds" includes organic and inorganic compounds.

The list of 65 toxic pollutants was developed by a multidisciplinary task force of scientists established by EPA. The task force conducted a scientific literature search and reviewed lists of toxic pollutants developed by other organizations. Pollutants were included by the task force in the list if:

(1) the pollutant had demonstrated carcinogenic, mutagenic, or teratogenic effects in humans or in laboratory animal testing, or had demonstrated a high degree of toxicity at low exposure levels to aquatic organisms or systems, and

(2) the pollutant was known or was strongly believed to be present in industrial discharges.[24]

The list of 65 toxic pollutants was judicially reviewed and accepted by the Federal District Court of the District of Columbia in NRDC v. Train, 8 ERC 2120 (1976). This decision settled four lawsuits against the EPA and approved a comprehensive strategy for the regulation of toxic pollutants under the Clean Water Act.[25]

EPA first published the list of 65 toxic pollutants on January 31, 1978 (43 FR 4108). Subsequently, EPA added the toxic pollutant list (Exhibit 2-12) to the federal regulations as part of the General Provisions for Effluent Guidelines and Standards, 40 CFR 401.15.[26]

PROPOSED REVISIONS OF THE TOXIC POLLUTANT LIST

Section 307(a)(1) authorizes EPA to revise the list of toxic pollutants, and specifies that to revise the list, EPA must consider:

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[24] Ridgeway M. Hall, Jr., "The Evolution and Implementation of EPA's Regulatory Program to Control the Discharge of Toxic Pollutants to the Nation's Waters," Natural Resources Lawyer, Volume X, Number 3, p. 518.

[25] The four lawsuits were: (1) NRDC v. Train, Civ. No. 2153-73, 6 ERC 1702 (D.D.C., May 23, 1974) where NRDC sued EPA to compel it to regulate more than nine compounds under Section 307(a) of the Act; (2) EDF et al. v. Train, Civ. No. 75-0172 (D.D.C.) where EPA was sued to compel it to promulgate final standards for the nine proposed; (3) Citizens for a Better Environment, et al. v. Train, Civ. No. 75-1698 (D.D.C.) where EPA was sued to compel it to promulgate nine final standards; and (4) NRDC v. Agee, et al., Civ. No. 75-1267 (D.D.C.) where NRDC sought an order for EPA to promulgate pretreatment standards under Section 307(b) for 35 industries.

[26] 44 FR 44502, July 30, 1979.

- the toxicity, persistence, and degradability of the pollutant,
- the usual or potential presence of the affected organisms in any waters,
- the importance of the affected organisms, and
- the nature and extent of the effect of the toxic pollutant on such organisms.

These are the same factors EPA was required to examine when designating pollutants as toxic under the 1973 version of the Clean Water Act. To further clarify the revision process, EPA issued guidance on factors to be included in petitions for revision of the toxic pollutant list.[27] These factors were not made part of the regulations, but EPA announced in the Federal Register that the guidance constituted the "information necessary to support any petition to the Environmental Protection Agency for a change in the toxic pollutant list."[28] The characteristics of a pollutant to be addressed in revised petitions are:

(1) Toxicity

(2) Persistence

(3) Bioaccumulation, Biomagnification, and Bioconcentration

(4) Synergistic Effects

(5) Water Solubility

(6) Extent of Point Source Discharges

(7) Exposure to Persons, Aquatic Organisms, and Wildlife

(8) Annual Production in United States

(9) Use Patterns

(10) Analytical Detection

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[27] 44 FR 18279, March 27, 1979.

[28] Ibid.

It is not necessary for a pollutant to demonstrate adverse effects in each of the enumerated areas for the pollutant to be listed as a toxic pollutant.[29]

As of January 1, 1981, EPA had proposed to add to the list of 65 toxic pollutants one chemical, ammonia.[30] EPA evaluated ammonia in terms of the ten characteristics of pollutants identified by the Agency's guidance. The results of this evaluation are displayed in Exhibit 2-13. In summary, EPA proposed the addition of ammonia because the chemical is highly toxic to aquatic life, highly water soluble, discharged from many point sources, found in ambient water concentrations exceeding "safe" concentrations,[31] present in U.S. waters with a significant potential for exposure, characterized by a high annual production, and measurable by existing techniques.

Following evaluation of public comments, EPA withdrew its proposal to add ammonia to the toxic pollutants list on December 1, 1980 (45 FR 79692). The Agency withdrew the proposal as a result of a change in its position on whether ammonia was found in ambient waters at concentration levels which posed human health risks. EPA concluded that ammonia was not normally present in ambient waters at concentrations toxic to warmwater fish species or harmful to human health. Furthermore, the Agency recognized that Water Quality Standards (under Section 301(g)) and technology-based effluent limitations (under Section 301(c)) provided adequate protection of aquatic organisms from point source ammonia discharges (45 FR 79692). EPA noted the inefficiency of controlling ammonia discharges by regulation under Section 307 since, by EPA's estimates, only 10 percent of ammonia discharged to U.S. waters would be subject to the regulations (the remainder of ammonia discharged comes from POTWs which would be unaffected by the proposed listing).

Dichlorodifluoromethane (F-12) and Trichlorofluoromethane (F-11). EPA proposed to remove dichlorodifluoromethane and trichlorofluoromethane from the toxic pollutants list on July 9, 1980 (45 FR 46103) in response to a petition from E.I. duPont de Nemours & Company requesting the removal of the two compounds.[32] The petition presented evidence and EPA concurred with the findings that:

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[29] Proposal To Add Ammonia, 45 FR 803, January 3, 1980.

[30] Ibid.

[31] EPA assumed the "safe" concentration was the EPA ambient water criterion of 20 ug/l (Quality Criteria for Water, 41 FR 32947, August 6, 1976.)

[32] F-11 and F-12 are listed under Halomethanes in the toxic pollutant list.

EXHIBIT 2-13

CRITERIA FOR ADDING AMMONIA TO THE TOXIC POLLUTANT LIST

Pollutant Characteristic	Evidence
Toxicity	(1) Un-ionized ammonia is acutely or chronically toxic to important freshwater and marine aquatic organisms. (2) Ammonia is readily oxidized to nitrite which is toxic to fish. (3) The oxidation of ammonia to nitrite and then to nitrate lowers the dissolved oxygen content of water and causes adverse effects to aquatic life. (4) Ammonia is not carcinogenic, teratogenic, or mutagenic in humans or animals. (5) The toxicity of ammonia is dependent upon the pH, temperature, and ionic strength of the water.
Persistence	Ammonia biodegrades in water and generally is not persistent.
Bioconcentration, Bioaccumulation, and Biomagnification	Ammonia does not have these characteristics.
Synergistic effects	Ammonia toxicity is increased by low levels of other pollutants such as dieldrin.
Water Solubility	Ammonia is highly water soluble.

Source: Toxic Pollutant List: Proposal to Add Ammonia, 45 FR 803, January 3, 1980.

EXHIBIT 2-13 (continued)

CRITERIA FOR ADDING AMMONIA TO THE TOXIC POLLUTANT LIST

Pollutant Characteristic	Evidence
Extent of point source discharges	(1) Toxic concentrations of ammonia are introduced into the aquatic environment through municipal sewage effluents, industrial dischargers (leather tanning, iron and steel, petroleum refining, glass, inorganics, nonferrous metals, ferroalloys and fertilizer industries), animal production for slaughtering, and fertilizer application. (2) Total ammonia concentrations in surface waters located near large metropolitan areas average 500 ug/l and higher. (3) Existing ambient water concentrations of un-ionized ammonia frequently exceed the EPA criterion of 20 ug/l ("Quality Criteria for Water," 41 FR 32947,August 6, 1976). (4) Ambient water ammonia concentrations were found to be highest near selected industrial discharges, sewage treatment plant effluent discharges, and near land under intense agricultural usage.
Exposure	There exists a significant potential for exposure of aquatic organisms and wildlife to ammonia.
Annual Production	High Annual Production.
Use Patterns	Most U.S. ammonia production is used in the manufacture of fertilizers, other inorganic and organic chemicals, and in the treatment of drinking water.
Analytical Detection	Analytical techniques can measure total ammonia concentrations as low as 10 ug/l in water.

- the nature of F-11 and F-12 and the methods of transportation and disposal of the compounds do not provide significant potential for contamination of water supplies;
- direct contact of the two compounds with water supplies results in "transient and low" contamination; and
- the mammalian and human toxicity of F-11 and F-12 are low.

The final rule deleting F-11 and F-12 from the toxic pollutant list was issued on January 8, 1981 (46 FR 2266).

Bis-(Chloromethyl) Ether (BCME). EPA proposed to remove Bis-(Chloromethyl) Ether from the toxic pollutant list on September 15, 1980 (45 FR 60942) because:

- it is not persistent and degrades immediately upon contact with water;
- it does not bioaccumulate;
- there is limited potential exposure of aquatic organisms; and
- it is not present in point source discharges.

EPA studied the carcinogenic properties of BCME and concluded that BCME does not present a risk to human health or to the environment by exposure from water (although BCME was shown to be carcinogenic to humans through air exposure). As of January, 1981, no final action had been taken because EPA is awaiting comment on the proposal from other program offices within the agency, e.g., air programs.[11]

Criteria Documents for the 65 Toxic Pollutants

EPA has issued water quality criteria documents for each of the 65 listed toxic pollutants in accordance with Section 304 of the Clean Water Act as amended in 1977. Revised criteria documents for 64 of the 65 toxic pollutants were published on November 28, 1980 (45 FR 79318). EPA announced that the last revised criteria document (for TCDD) will be published by March 1, 1981. EPA will use the criteria documents as guides when establishing effluent standards for the toxic pollutants.

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[11] Personal communication with staff of the Criteria and Standards Division, Office of Water Planning and Standards, EPA on January 14, 1981.

Criteria documents must reflect the latest scientific knowledge on the identifiable effects of pollutants on public health, public welfare, aquatic life, and recreation. In addition, the Consent Decree in Natural Resources Defense Council, et al., v. Train, 8 ERC 2120 (D.D.C. 1976) specified that the criteria documents must state the maximum recommended concentrations for each pollutant which will protect aquatic life and human health with an "ample margin of safety". This recommended concentration level is referred to as the ambient water criterion and normally is expressed in micrograms per liter (ug/l) or the equivalent measurement of parts per billion (ppb). Ambient water criteria must be based solely on data and scientific judgment, and must not reflect considerations of economic or technological feasibility.

EPA developed three ambient water criteria numbers for each chemical. The three criteria were derived to protect freshwater aquatic life, saltwater aquatic life, and human health. Separate water quality criteria were developed for freshwater and saltwater organisms because some substances may be more toxic in fresh water than in salt water, or vice versa.[14] In general, EPA issued one ambient water criterion as a 24-hour average and another as the ceiling concentration never to be exceeded at any one time.

The types of information to be included in criteria documents are outlined in Appendices to the Water Quality Criteria (44 FR 15926):

- Appendix B--Guidelines for Deriving Water Quality Criteria for the Protection of Aquatic Life and Its Uses, and

- Appendix C--Guidelines and Methodology Used in the Preparation of Health Effect Assessment Chapters of the Consent Decree Water Criteria Documents.

The guidelines describe a consistent way of using available data to derive ambient water criteria numbers.

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[14] "Guidelines for Deriving Water Quality Criteria for the Protection of Aquatic Life and Its Uses," Appendix B to Water Quality Criteria, 44 FR 15926, March 15, 1979.

DESIGNATING AND CONTROL OF DISCHARGES OF HAZARDOUS SUBSTANCES (SECTION 311)--REGULATORY REVIEW

BACKGROUND

In accordance with Section 311 of the Clean Water Act,[1] EPA promulgated 4 sets of regulations to control the discharge of hazardous substances.[2] 40 CFR 116 designated 271 substances as hazardous, 40 CFR 117 addressed the removability of hazardous substances, 40 CFR 118 established rules for the determination of harmful quantities of hazardous substances, and 40 CFR 119 set forth the methods and procedures for determining and assessing civil penalties for the discharge of hazardous substances in harmful quantities.[3]

Prior to their effective date, the hazardous substances regulations were challenged in a law suit.[4] Parts 117 and 118 were invalidated by order of a Federal District Court; Part 116 was not affected by the ruling. As a result of this lawsuit, Section 311 of the Clean Water Act was amended on November 2, 1978 by the enactment of Public Law 95-576. The requirement for determination of harmful quantities was changed to determinations of quantities "which may be harmful."[5] The amended statute no longer requires EPA to make determinations of removability or units of measurement for computing penalties.

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[1] Section 311(b)(2)(A) of the Clean Water Act authorizes EPA to promulgate regulations designating as hazardous substances, other than oil, "such elements and compounds which, when discharged in any quantity into or upon the navigable waters of the United States or adjoining shorelines, . . . present an imminent and substantial danger to the public health or welfare including, but not limited to, fish, shellfish, wildlife, shorelines, and beaches" (emphasis added).

[2] According to the regulations, 40 CFR 116.3, "'Discharge' includes, but is not limited to any spilling, leaking, pumping, pouring, emitting, emptying, or dumping." Types of discharges excluded from coverage are discussed later in the paper.

[3] 43 FR 10474, March 13, 1978.

[4] See *Manufacturing Chemists Association, et al. v. Costle, et al.* 455 F.Supp. 968 (W.D. La., 1978).

[5] Clean Water Act, Section 311(b)(4).

On February 16, 1979, EPA revoked Parts 117, 118, and 119. The Agency proposed a new Part 117 which contained many of the provisions from the former Part 118. The most salient change made was that the Part 118 term "harmful quantity" was replaced by "reportable quantity." Final regulations for the determination of reportable quantities for hazardous substances discharges, 40 CFR 117, were issued on August 29, 1979.[6]

These events are summarized in Exhibit 2-14.

DESIGNATION OF HAZARDOUS SUBSTANCES

EPA has developed a two part selection process for designating hazardous substances.[7] First, elements and compounds are evaluated against toxicological selection criteria. Candidate substances which meet at least one of the toxicological criteria are further examined for discharge potential. This use of discharge potential criteria limits the candidate substances to a practical number and establishes priority of designation. It is important to note that discharge potential criteria do not preclude subsequent designations of substances initially not designated. The two types of criteria are reviewed in detail below.

The elements and compounds appearing in Exhibit 2-15 have met both the toxicological selection criteria and the discharge potential screening criteria.[8] Thus, EPA in final rulemakings has designated them as hazardous substances in 40 CFR 116.

Toxicological Selection Criteria

To determine toxicological effects of chemicals, EPA specified that the toxicity of elements, compounds, and structural isomers should be evaluated in:

- aquatic animals,
- mammals, or

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[6] 44 FR 50766 (August 29, 1979).

[7] Designated hazardous substances include "any isomers and hydrates, as well as any solutions and mixtures containing these substances." The regulations define "mixture" as "any combination of two or more elements and/or compounds in solid, liquid, or gaseous form except where such substances have undergone a chemical reaction so as to become inseparable by physical means" (40 CFR 116.4). There is no minimum concentration requirement.

[8] 40 CFR 116.4.

EXHIBIT 2-14

SECTION 311 HAZARDOUS SUBSTANCES: REGULATORY CHRONOLOGY

October 18, 1972. Section 311 of the Federal Water Pollution Control Act enacted.

December 30, 1975. EPA publishes (40 FR 59960):

- proposed rules for designation of hazardous substances, 40 CFR 116.
- proposed rules for determination of removability of hazardous substances, 40 CFR 117.
- proposed rules for determination of harmful quantities for hazardous substances, 40 CFR 118.
- proposed rules for determination of units of measurement and rates of penalty for hazardous substances, 40 CFR 119.

March 13, 1978. EPA publishes (43 FR 10474):

- final rule designating 271 hazardous substances, 40 CFR 116.
- final rule determining the removability of hazardous substances, 40 CFR 117.
- final rule defining "harmful quantities" for reporting and penalty provisions, 40 CFR 118 and 119.
- proposed designation of 28 additional hazardous substances, 40 CFR 116.

June 8, 1978. Preliminary injunction granted, *MCA v. Costle*, 11 ERC 1793 (W.D.La.)

August 4, 1978. Permanent injunction granted; regulation defining "harmful quantities" invalidated, *MCA v. Costle*, 11 ERC 2015 (W.D.La.)

November 2, 1978. Clean Water Act, Section 311, amended by Public Law 95-576.

- "harmful quantities" replaced by "reportable quantitites".

EXHIBIT 2-14 (continued)

SECTION 311 HAZARDOUS SUBSTANCES: REGULATORY CHRONOLOGY

- EPA no longer required to make determinations of removability or units of measurement.

February 16, 1979. EPA publishes (43 FR 10266):

- final rules designating 28 additional hazardous substances, 40 CFR 116.
- revocation of 40 CFR 117; 40 CFR 118; and 40 CFR 119.
- proposed rules for new 40 CFR 117: Determination of Reportable Quantities for Hazardous Substances.

August 29, 1979. EPA publishes (44 FR 50766):

- final rules for the determinaton of reportable quantities of 299 hazardous substances, 40 CFR 117.
- proposed rule for removal of calcium oxide and calcium hydroxide ("lime") from the hazardous substances list.

November 13, 1979. EPA publishes (44 FR 65400):

- final rule deleting calcium oxide and calcium hydroxide from the hazardous substances list.

July 9, 1980. EPA publishes (45 FR 46094):

- proposed amendment to 40 CFR 116 expanding the criteria for designating hazardous substances to include carcinogenic effects on humans; proposal adds 14 substances to hazardous substances list on the basis of carcinogenicity.
- proposed amendment to 40 CFR 117 adding reportable quantities for substances proposed as hazardous on the basis of carcinogenicity.

- aquatic flora.[9]

Exhibit 2-16 displays the specific toxicological screening requirements for chemical substances. Chemicals which meet one of these criteria are referred to as "candidate substances" and are further evaluated against discharge potential criteria. Although there are five possible toxicological criteria, thus far, EPA has based the designations of chemical substances as hazardous solely on aquatic animal toxicity.

Discharge Potential Screening Criteria

In order to make the designation of hazardous substances a manageable process, EPA further screens candidates for designation on the basis of a chemical's propensity for discharge. Under Section 311 of the Clean Water Act, it is not mandatory to consider the discharge potential of a chemical before designating the chemical as a hazardous substance. However, EPA believes it is appropriate to restrict designation to those elements and compounds which are most likely to be discharged in harmful quantities.[10]

The factors used by the Agency to assess discharge potential are:

(1) production quantities,

(2) past history of discharge,

(3) use and distribution patterns, and

(4) cost of the substance.

Candidate substances are designated as hazardous substances if they have:

(1) a spill history,

(2) an annual production equal to or greater than 1 billion pounds,

(3) an annual production of less than 1 billion pounds, and are used primarily as pesticides, or

(4) an annual production of less than 1 billion pounds, and have relatively low market prices and relatively high toxicity.

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[9] 43 FR 10474 (March 13, 1978).

[10] Preamble to 40 CFR 116, 43 FR 10478 (March 13, 1978).

EXHIBIT 2-15

LIST OF DESIGNATED HAZARDOUS SUBSTANCES

Common Name	Synonyms	Category	RQ in Pounds (Kilograms)
Acetaldehyde	Ethanal, ethyl aldehyde, acetic aldehyde	C	1,000 (454)
Acetic acid	Glacial acetic acid, vinegar acid	C	1,000 (454)
Acetic anhydride	Acetic oxide, acetyl oxide	C	1,000 (454)
Acetone cyanohydrin	2-methyllactonitrile, alphahydroxyisobutyronitrile	A	10 (4.54)
Acetyl bromide		D	5,000 (2,270)
Acetyl chloride		D	5,000 (2,270)
Acrolein	2-propenal, acrylic aldehyde, acrylaldehyde, acraldehyde	X	1 (0.454)
Acrylonitrile	Cyanoethylene, Fumigrain, Ventox, propeneitrile, vinyl cyanide	B	100 (45.4)
Adipic acid	Hexanedioic acid	D	5,000 (2,270)
Aldrin	Octalene, HHDN	X	1 (0.454)
Allyl alcohol	2-propen-1-ol, 1-propenol-3, vinyl carbinol	B	100 (45.4)
Allyl chloride	3-chloropropene, 3-chloropropylene Chlorallylene	C	1,000 (454)
Aluminum sulfate	Alum	D	5,000 (2,270)
Ammonia		B	100 (45.4)
Ammonium acetate	Acetic acid ammonium, salt	D	5,000 (2,270)
Ammonium benzoate		D	5,000 (2,270)
Ammonium bicarbonate	Acid ammonium carbonate, ammonium hydrogen carbonate	D	5,000 (2,270)
Ammonium bichromate		C	1,000 (454)
Ammonium bifluoride	Acid ammonium fluoride, ammonium hydrogen fluoride	D	5,000 (2,270)
Ammonium bisulfite		D	5,000 (2,270)
Ammonium carbamate	Ammonium aminoformate	D	5,000 (2,270)
Ammonium carbonate		D	5,000 (2,270)
Ammonium chloride	Ammonium muriate, sal ammoniac,	D	5,000 (2,270)
Ammonium chromate		C	1,000 (454)
Ammonium citrate dibasic	Diammonium citrate, citric acid diammonium salt	D	5,000 (2,270)
Ammonium fluoborate	Ammonium fluoroborate, ammonium borofluoride	D	5,000 (2,270)

EXHIBIT 2-15

LIST OF DESIGNATED HAZARDOUS SUBSTANCES
(continued)

Common Name	Synonyms	Category	RQ in Pounds (Kilograms)	
Ammonium fluoride	Neutral ammonium fluoride	D	5,000	(2,270)
Ammonium hydroxide		C	1,000	(454)
Ammonium oxalate		D	5,000	(2,270)
Ammonium silicofluoride	Ammonium fluosilicate	C	1,000	(454)
Ammonium sulfamate	Ammate, AMS, ammonium amidosulfate	D	5,000	(2,270)
Ammonium sulfide		D	5,000	(2,270)
Ammonium sulfite		D	5,000	(2,270)
Ammonium tartrate	Tartaric acid ammonium salt	D	5,000	(2,270)
Ammonium thiocyanate	Ammonium rhodanide, ammonium sulfocyanate, ammonium sulfocyanide	D	5,000	(2,270)
Ammonium thiosulfate	Ammonium hyposulfite	D	5,000	(2,270)
Amyl acetate	Amylacetic ester, pear oil banana oil	C	1,000	(454)
Aniline	Aniline oil, phenylamine, aminobenzene, aminophen, kyanol	C	1,000	(454)
Antimony pentachloride		C	1,000	(454)
Antimony potassium tartrate	Tartar emetic, tartrated antimony, tartar, d antimony, potassium antimonyltartrate	C	1,000	(454)
Antimony tribromide		C	1,000	(454)
Antimony trichloride	Butter of antimony	C	1,000	(454)
Antimony trifluoride	Antimony fluoride	C	1,000	(454)
Antimony trioxide	Diantimony trioxide, flowers of antimony	D	5,000	(2,270)
Arsenic disulfide	Red arsenic sulfide	D	5,000	(2,270)
Arsenic pentoxide	Arsenic acid anhydride, arsenic oxide	D	5,000	(2,270)
Arsenic trichloride	Arsenic chloride, arsenious chloride arsenous chloride, butter of arsenic	D	5,000	(2,270)
Arsenic trioxide	Arsenious acid, arsenious oxide, white arsenic	D	5,000	(2,270)
Arsenic trisulfide	Arsenious sulfide, yellow arsenic sulfide	D	5,000	(2,270)
Barium cyanide		A	10	(4.54)
Benzene	Cyclohexatriene, benzol	C	1,000	(454)
Benzoic acid	Benzenecarboxylic acid, phenylformic acid, dracylic acid	D	5,000	(2,270)

EXHIBIT 2-15

LIST OF DESIGNATED HAZARDOUS SUBSTANCES
(continued)

Common Name	Synonyms	Category	RQ in Pounds (Kilograms)	
Benzonitrile	Phenyl cyanide, cyanobenzene	C	1,000	(454)
Benzoyl chloride	Benzenecarbonyl chloride	C	1,000	(454)
Benzyl chloride		B	100	(45.4)
Beryllium chloride		D	5,000	(2,270)
Beryllium fluoride		D	5,000	(2,270)
Beryllium nitrate		D	5,000	(2,270)
n-butyl phthalate	1,2-benzenedicarboxylic acid, dibutyl ester, dibutyl phthalate	B	100	(45.4)
Butyl acetate	Acetic acid butyl ester	D	5,000	(2,270)
Butylamine	1-aminobutane	C	1,000	(454)
Butyric acid	Butanoic acid, ethylacetic acid	D	5,000	(2,270)
Cadmium acetate		B	100	(45.4)
Cadmium bromide		B	100	(45.4)
Cadmium chloride		B	100	(45.4)
Calcium arsenate	Tricalcium orthoarsenate	C	1,000	(454)
Calcium arsenite		C	1,000	(454)
Calcium carbide	Carbide, acetylenogen	D	5,000	(2,270)
Calcium chromate	Calcium chrome yellow, geblin, yellow ultramarine	C	1,000	(454)
Calcium cyanide		A	10	(4.54)
Calcium dodecylbenzenesulfonate		C	1,000	(454)
Calcium hypochlorite		B	100	(45.4)
Captan	Orthocide-406, SR-406, Vancide-89	A	10	(4.54)
Carbaryl	Sevin	B	100	(45.4)
Carbofuran		A	10	(4.54)
Carbon disulfide	Carbon bisulfide, dithiocarbonic anhydride	D	5,000	(2,270)
Carbon tetrachloride	Tetrachloromethaneane, Perchloromethane	D	5,000	(2,270)
Chlordane	Toxichlor, chlordan	X	1	(0.454)
Chlorine		A	10	(4.54)
Chlorobenzene	Monochlorobenzene benzene chloride	B	100	(45.4)

EXHIBIT 2-15

LIST OF DESIGNATED HAZARDOUS SUBSTANCES
(continued)

Common Name	Synonyms	Category	RQ in Pounds (Kilograms)
Chloroform	Trichloromethane	D	5,000 (2,270)
Chlorpyrifos	Dursban	X	1 (0.454)
Chlorosulfonic acid	Sulfuric chlorohydrin	C	1,000 (454)
Chromic acetate		C	1,000 (454)
Chromic acid	Chromic anhydride, chromium trioxide	C	1,000 (454)
Chromic sulfate		C	1,000 (454)
Chromous chloride		C	1,000 (454)
Cobaltous bromide	Cobalt bromide	C	1,000 (454)
Cobaltous formate	Cobalt formate	C	1,000 (454)
Cobaltous sulfamate	Cobalt sulfamate	C	1,000 (454)
Coumaphos	Co-Ral	A	10 (4.54)
Cresol	Cresylic acid, Hydroxytoluene	C	1,000 (454)
Crotonaldehyde	2-butenal propylene aldehyde	B	100 (45.4)
Cupric acetate	Copper acetate, crystalized verdigris	B	100 (45.4)
Cupric acetoarsenite	Copper acetoarsenite, copper acetate arsenite, Paris green	B	100 (45.4)
Cupric chloride	Copper chloride	A	10 (4.54)
Cupric Nitrate	Copper nitrate	B	100 (45.4)
Cupric oxalate	Copper oxalate	B	100 (45.4)
Cupric sulfate	Copper sulfate	A	10 (4.54)
Cupric sulfate, ammoniated	Ammoniated copper sulfate	B	100 (45.4)
Cupric tartrate	Copper tartrate	B	100 (45.4)
Cyanogen chloride		A	10 (4.54)
Cyclohexane	Hexahydrobenzene, hexamethylene, hexanaphthene	C	1,000 (454)
2,4-D acid	2,4-dichlorophenoxyacetic acid	B	100 (45.4)
2,4-D ester	2,4-dichlorophenoxyacetic acid ester	B	100 (45.4)
DDT	p,p'-DDT	X	1 (0.454)
Diazinon	Dipofene, Diazitol, Basudin, Spectracide	X	1 (0.454)
Dicamba	2-methoxy-3,6-dichlorobenzoic acid	C	1,000 (454)
Dichlobenil	2,6-dichlorobenzonitrile, 2,6-DBN	C	1,000 (454)

EXHIBIT 2-15

LIST OF DESIGNATED HAZARDOUS SUBSTANCES
(continued)

Common Name	Synonyms	Category	RQ in Pounds (Kilograms)	
Dichlone	Phygon, dichloronaphthoquinone	X	1	(0.454)
Dichlorobenzene	Di-chloride, Paramoth (Para)	B	100	(45.4)
Dichloropropane	Propylene dichloride	D	5,000	(2,270)
Dichloropropene		D	5,000	(2,270)
Dichloropropene-dichloropropane (mixture)	D-D mixture, Vidden D	D	5,000	(2,270)
2,2-Dichloropropionic acid	Dalapon	D	5,000	(2,270)
Dichlorvos	2,2-dichlorovinyl dimethyl phosphate Vapona	A	10	(4.54)
Dieldrin	Alvit	X	1	(0.454)
Diethylamine		C	1,000	(454)
Dimethylamine		C	1,000	(454)
Dinitrobenzene (mixed)	Dinitrobenzol	C	1,000	(454)
Dinitrophenol	Aldifen	C	1,000	(454)
Dinitrotoluene	DNT	C	1,000	(454)
Diquat	Aquacide, Dextrone, Regione, Diquat dibromide	C	1,000	(454)
Disulfoton	Di-syston	X	1	(0.454)
Diuron	DCMU, DMU	B	100	(45.4)
Dodecylbenzenesulfonic acid		C	1,000	(454)
Endosulfan	Thiodan	X	1	(0.454)
Endrin	Mendrin, Compound 269	X	1	(0.454)
Epichlorohydrin	Chloropropylene oxide	C	1,000	(454)
Ethion	Nialate, ethyl methylene, phosphorodithioate	A	10	(4.54)
Ethylbenzene	Phenylethane	C	1,000	(454)
Ethylenediamine	1,2-diaminoethane	C	1,000	(454)
Ethylenediaminetetra-acetic acid (EDTA)	Edetic acid, Havidote, (ethylenedinitrilo)-tetraacetic acid	D	5,000	(2,270)
Ethylene dibromide	1,2-dibromoethane acetylene dibromide sym-dibromoethylene	C	1,000	(454)
Ethylene dichloride	1,2-dichloroethane, sym-bichloroethane	D	5,000	(2,270)

EXHIBIT 2-15

LIST OF DESIGNATED HAZARDOUS SUBSTANCES
(continued)

Common Name	Synonyms	Category	RQ in Pounds (Kilograms)	
Ferric ammonium citrate	Ammonium ferric citrate	C	1,000	(454)
Ferric ammonium oxalate	Ammonium ferric oxalate	C	1,000	(454)
Ferric chloride	Flores martis, iron trichloride	C	1,000	(454)
Ferric fluoride		B	100	(45.4)
Ferric nitrate	Iron nitrate	C	1,000	(454)
Ferric sulfate	Ferric persulfate, ferric sesquisulfate, ferric tersulfate	C	1,000	(454)
Ferrous ammonium sulfate	Mohr's salt, iron ammonium sulfate	C	1,000	(454)
Ferrous chloride	Iron chloride, iron dichloride, iron protochloride	B	100	(45.4)
Ferrous sulfate	Green vitriol, Iron vitriol, iron sulfate, iron protosulfate	C	1,000	(454)
Formaldehyde	Methyl aldehyde, methanal, formalin	C	1,000	(454)
Formic acid	Methanoic acid	D	5,000	(2,270)
Fumaric acid	Trans-butenedioic acid, trans-1,2-ethylenedicarboxylic acid, boletic acid, allomaleic acid	D	5,000	(2,270)
Furfural	2-furaldehyde, pyromucic aldehyde	C	1,000	(454)
Guthion	Gusathion, azinphos-methyl	X	1	(0.454)
Heptachlor	Velsicol-104, Drinox, Heptagran	X	1	(0.454)
Hexachlorocyclopentadiene	Perchlorocyclopentadiene	X	1	(0.454)
Hydrochloric acid	Hydrogen chloride, muriatic acid	D	5,000	(2,270)
Hydrofluoric acid	Fluorhydric acid	D	5,000	(2,270)
Hydrogen cyanide	Hydrocyanic acid	A	10	(4.54)
Hydrogen sulfide	Hydrosulfuric acid, sulfur hydride	B	100	(45.4)
Isoprene	2-methyl-1,3-butadiene	C	1,000	(454)
Isopropanolamine dodecylbenzenesulfonate		C	1,000	(454)
Kelthane	Di(p-chlorophenyl)-trichloromethylcarbinol, DTMC, dicofol	D	5,000	(2,270)
Kepone	Chlordecone 1,1a,3,3a,4,5,5,5a,5b,6-decachlorooctahydro-1,3,4-metheno-2H-cyclobuta(cd)pentalen-2-one	X	1	(0.454)

EXHIBIT 2-15

LIST OF DESIGNATED HAZARDOUS SUBSTANCES
(continued)

Common Name	Synonyms	Category	RQ in Pounds (Kilograms)	
Lead acetate	Sugar of lead	D	5,000	(2,270)
Lead arsenate		D	5,000	(2,270)
Lead chloride		D	5,000	(2,270)
Lead fluoborate	Lead fluoroborate	D	5,000	(2,270)
Lead fluoride	Lead difluoride, plumbous fluoride	C	1,000	(454)
Lead iodide		D	5,000	(2,270)
Lead nitrate		D	5,000	(2,270)
Lead stearate	Stearic acid lead salt	D	5,000	(2,270)
Lead sulfate		D	5,000	(2,270)
Lead sulfide	Galena	D	5,000	(2,270)
Lead thiocyanate	Lead sulfocyanate	D	5,000	(2,270)
Lindane	Gamma-BHC, gamma-benzene hexachloride	X	1	(0.454)
Lithium chromate		C	1,000	(454)
Malathion	Phospothion	C	1,000	(454)
Maleic acid	Cis-butenedioic acid, cis-1,2-ethylene-dicarboxylic acid, toxilic acid	D	5,000	(2,270)
Maleic anhydride	2,5-furandione, cis-butenedioic anhydride, toxilic anhydride	D	5,000	(2,270)
Mercaptodimethur	Mesurol	B	100	(45.4)
Mercuric cyanide	Mercury cyanide	X	1	(0.454)
Mercuric nitrate	Mercury nitrate, mercury pernitrate	A	10	(4.54)
Mercuric sulfate	Mercury sulfate, mercury persulfate	A	10	(4.54)
Mercuric thiocyanate	Mercury thiocyanate, mercuric sulfocyanate, mercuric sulfocyanide	A	10	(4.54)
Mercurous nitrate	Mercury protonitrate	A	10	(4.54)
Methoxychlor	DMDT, methoxy-DDT	X	1	(0.454)
Methyl mercaptan	Methanethiol, mercaptomethane, methyl sulfhydrate, thiomethyl alcohol	B	100	(45.4)
Methyl methacrylate	Methacrylic acid methyl ester, methyl-2-methyl-2-propenoate	D	5,000	(2,270)
Methyl parathion	Nitrox-80	B	100	(45.4)
Mevinphos	Phosdrin	X	1	(0.454)
Mexacarbate	Zectran	C	1,000	(454)

EXHIBIT 2-15

LIST OF DESIGNATED HAZARDOUS SUBSTANCES
(continued)

Common Name	Synonyms	Category	RQ in Pounds (Kilograms)	
Monoethylamine	Ethylamine, aminoethane	C	1,000	(454)
Monomethylamine	Methylamine, aminomethane	C	1,000	(454)
Naled	Dibrom	A	10	(4.54)
Naphthalene	White tar, tar camphor, naphthalin	D	5,000	(2,270)
Naphthenic acid	Cyclohexanecarboxylic acid, hexahydrobenzoic acid	B	100	(45.4)
Nickel ammonium sulfate	Ammonium nickel sulfate	D	5,000	(2,270)
Nickel chloride	Nickelous chloride	D	5,000	(2,270)
Nickel hydroxide	Nickelous hydroxide	C	1,000	(454)
Nickel nitrate		D	5,000	(2,270)
Nickel sulfate	Nickelous sulfate	D	5,000	(2,270)
Nitric acid	Aqua fortis	C	1,000	(454)
Nitrobenzene	Nitrobenzol, oil of mirbane	C	1,000	(454)
Nitrogen dioxide	Nitrogen tetraoxide	C	1,000	(454)
Nitrophenol (mixed)	Mononitrophenol	C	1,000	(454)
Nitrototuene		C	1,000	(454)
Paraformaldehyde	Paraform, Formagene, Triformol, polymerized formaldehyde, polyoxymethylene	C	1,000	(454)
Parathion	DNTP, Niran	X	1	(0.454)
Pentachlorophenol	PCP, Penta	A	10	(4.54)
Phenol	Carbolic acid, phenyl hydroxide, hydroxybenzene, oxybenzene	C	1,000	(454)
Phosgene	Diphosgene, carbonyl chloride, chloroformyl chloride	D	5,000	(2,270)
Phosphoric acid	Orthophosphoric acid	D	5,000	(2,270)
Phosphorus	Black phosphorus, red phosphorus, white phosphorus, yellow phosphorus	X	1	(0.454)
Phosphorus oxychloride	Phosphoryl chloride, phosphorus chloride	D	5,000	(2,270)
Phosphorus pentasulfide	Phosphoric sulfide, thiophosphoric anhydride, phosphorus persulfide	B	100	(45.4)
Phosphorus trichloride	Phosphorous chloride	D	5,000	(2,270)
Polychorinated biphenyls	PCB, Aroclor, polychlorinated diphenyls	A	10	(4.54)

EXHIBIT 2-15

LIST OF DESIGNATED HAZARDOUS SUBSTANCES
(continued)

Common Name	Synonyms	Category	RQ in Pounds	(Kilograms)
Potassium arsenate		C	1,000	(454)
Potassium arsenite	Potassium metaarsenite	C	1,000	(454)
Potassium bichromate	Potassium dichromate	C	1,000	(454)
Potassium chromate		C	1,000	(454)
Potassium cyanide		A	10	(4.54)
Potassium hydroxide	Potassium hydrate, caustic potash, potassa	C	1,000	(454)
Potassium permanganate	Chameleon mineral	B	100	(45.4)
Propargite	Omite	A	10	(4.54)
Propionic acid	Propanoic acid, methylacetic acid, ethylformic acid	D	5,000	(2,270)
Propionic anhydride	Propanoic anhydride, methylacetic anhydride	D	5,000	(2,270)
Propylene oxide	Propene oxide	D	5,000	(2,270)
Pyrethrins	Pyrethrin I, Pyrethrin II	C	1,000	(454)
Quinoline	1-benzazine, benzo(b)pyridine, leuocoline, chinoleine, leucol	C	1,000	(454)
Resorcinol	Resorcin, 1,3-benzenediol, meta-dihydroxybenzene	C	1,000	(454)
Selenium oxide	Selenium dioxide	C	1,000	(454)
Silver nitrate	Nitric acid silver, (1+) salt, lunar caustic	X	1	(0.454)
Sodium	Natrium	C	1,000	(454)
Sodium arsenate	Disodium arsenate	C	1,000	(454)
Sodium arsenite	Sodium metaarsenite	C	1,000	(454)
Sodium bichromate	Sodium dichromate	C	1,000	(454)
Sodium bifluoride		D	5,000	(2,270)
Sodium bisulfite	Sodium acid, sulfite, sodium hydrogen sulfite	D	5,000	(2,270)
Sodium chromate		C	1,000	(454)
Sodium cyanide		A	10	(4.54)
Sodium dodecylbenzenesulfonate		C	1,000	(454)
Sodium fluoride	Villiaumite	D	5,000	(2,270)

EXHIBIT 2-15

LIST OF DESIGNATED HAZARDOUS SUBSTANCES
(continued)

Common Name	Synonyms	Category	RQ in Pounds (Kilograms)
Sodium hydrosulfide	Sodium hydrogen sulfide	D	5,000 (2,270)
Sodium hydroxide	Caustic soda, soda lye, sodium hydrate	C	1,000 (454)
Sodium hypochlorite	Bleach	B	100 (45.4)
Sodium methylate	Sodium methoxide	C	1,000 (454)
Sodium nitrite		B	100 (45.4)
Sodium phosphate, dibasic		D	5,000 (2,270)
Sodium phosphate, tribasic		D	5,000 (2,270)
Sodium selenite		C	1,000 (454)
Strontium chromate		C	1,000 (454)
Strychnine		A	10 (4.54)
Styrene	Vinylbenzene, phenylethylene, styrol, styrolene, cinnamene, cinnamol	C	1,000 (454)
Sulfuric acid	Oil of vitriol, oleum	C	1,000 (454)
Sulfur monochloride	Sulfur chloride	C	1,000 (454)
2,4,5-T acid	2,4,5-trichlorophenoxy acetic acid	B	100 (45.4)
2,4,5-T amines	Acetic acid (2,4,5-trichlorophenoxy)-compound with N,N-dimethylmethanamine(1:1)	B	100 (45.4)
	Acetic acid (2,4,5-trichlorophenoxy)-compound with N-methyl-methanamine(1:1)	B	100 (45.4)
	Acetic acid (2,4,5-trichlorophenoxy)-compound with 1-amino-2-propanol(1:1)	B	100 (45.4)
	Acetic acid (2,4,5-trichlorophenoxy)-compound with 2,2'2'-nitrilotris [ethanol](1:1)	B	100 (45.4)
2,4,5-T esters	2,4,5-trichlorophenoxy acetic esters	B	100 (45.4)
2,4,5-T salts	Acetic acid (2,4,5-trichlorophenoxy)-sodium salt	B	100 (45.4)
2,4,5-TP acid	Propanoic acid 2-(2,4,5-trichlorophenoxy)	B	100 (45.4)
2,4,5-TP esters	Propanoic acid, 2-(2,4,5-trichlorophenoxy)-, isooctyl ester	B	100 (45.4)
TDE	DDD	X	1 (0.454)

EXHIBIT 2-15

LIST OF DESIGNATED HAZARDOUS SUBSTANCES
(continued)

Common Name	Synonyms	Category	RQ in Pounds (Kilograms)	
Tetraethyl lead	Lead tetraethyl, TEL	B	100	(45.4)
Tetraethyl pyrophosphate	TEPP	B	100	(45.4)
Toluene	Toluol, methylbenzene, phenylmethane, Methacide	C	1,000	(454)
Toxaphene	Camphechlor	X	1	(0.454)
Trichloroethylene	Ethylene trichloride	C	1,000	(454)
Trichlorfon	Dipterex, Dylox	C	1,000	(454)
Trichlorophenol	Collunosol, Dowicide 2 or 2S, Omal, Phenachlor	A	10	(4.54)
Triethanolamine dodecylbenzenesulfonate		C	1,000	(454)
Triethylamine		D	5,000	(2,270)
Trimethylamine	TMA	C	1,000	(454)
Uranyl acetate		D	5,000	(2,270)
Uranyl nitrate		D	5,000	(2,270)
Vanadium pentoxide	Vanadic anhydride, vanadic acid anhydride	C	1,000	(454)
Vanadyl sulfate	Vanadic sulfate, vanadium sulfate	C	1,000	(454)
Vinyl acetate	Acetic acid ethylene ether	C	1,000	(454)
Vinylidene chloride	1,1-dichloroethylene, 1,1-dichloroethene	D	5,000	(2,270)
Xylene (mixed)	Dimethylbenzene, Xylol	C	1,000	(454)
Xylenol	Dimethylphenol, hydroxydimethylbenzene	C	1,000	(454)
Zinc acetate		C	1,000	(454)
Zinc ammonium chloride		D	5,000	(2,270)
Zinc borate		C	1,000	(454)
Zinc bromide		D	5,000	(2,270)
Zinc carbonate		C	1,000	(454)
Zinc chloride	Butter of zinc	D	5,000	(2,270)
Zinc cyanide		A	10	(4.54)
Zinc fluoride		C	1,000	(454)
Zinc formate		C	1,000	(454)
Zinc hydrosulfite		C	1,000	(454)

EXHIBIT 2-15

LIST OF DESIGNATED HAZARDOUS SUBSTANCES
(continued)

Common Name	Synonyms	Category	RQ in Pounds	(Kilograms)
Zinc nitrate		D	5,000	(2,270)
Zinc phenolsulfonate	Zinc sulfocarbolate	D	5,000	(2,270)
Zinc phosphide		C	1,000	(454)
Zinc silicofluoride	Zinc fluorsilicate	D	5,000	(2,270)
Zinc sulfate	White vitriol, zinc vitriol, white copperas	C	1,000	(454)
Zirconium nitrate		D	5,000	(2,270)
Zirconsium potassium fluoride		D	5,000	(2,270)
Zirconsium sulfate	Disulfatozirconic acid	D	5,000	(2,270)
Zirconium tetrachloride		D	5,000	(2,270)

Exhibit 2-16

TOXICOLOGICAL SELECTION CRITERIA FOR DESIGNATING HAZARDOUS SUBSTANCES[a]

Species	Concentration[b]	Time Exposed	Response	Total Experiment Time
Aquatic Animals	500 mg/l[c]	continuous exposure	Lethal to 1/2 of Test Population	96 hours
Mammals				
- oral exposure	50 mg/kg body weight	single dose	Lethal to 1/2 of Test Population	14 days
- dermal exposure	200 mg/kg body weight	24 hours	Lethal to 1/2 of Test Population	14 days
- vapor exposure	20 cc/m^3 air	1 hour	Lethal to 1/2 of Test Population	14 days
Aquatic Flora	100 mg/l (ppm)	continuous exposure	Lethal, measured by 50% decrease in cell count, biomass, or photosynthetic ability	14 days

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[a] Source: Designation of Hazardous Substances: 40 CFR 116, 43 FR 10474, March 13, 1978.

[b] Abbreviations: mg/l = milligram(s) per liter cc/m^3 = cubic centimeters per cubic meter
mg/kg = milligram(s) per kilogram ppm = parts per million

[c] 500 mg/l is the LC50 which means "that concentration of material which is lethal to one-half of the test population of aquatic animals upon continuous exposure for 96 hours or less." (40 CFR 116.4).

EPA relied on production quantity to assess discharge potential because Department of Transportation and Environmental Protection Agency records indicated that chemicals which were most abundant in commerce were, in general, the chemicals spilled most frequently.[11] The cut-off point of one billion pounds was chosen by the Agency as a result of an analysis which indicated that chemicals produced in excess of one billion pounds annually are commonly used in highly diversified products and processes. They are handled and transported in large quantities, and typically have low selling prices. Since these chemicals are transported in large quantities, EPA assumes that they are the most abundant in commerce, and thus, are spilled most frequently. Candidate chemicals produced in excess of one billion pounds annually were automatically designated as hazardous substances.

Candidate chemicals produced in quantities less than one billion pounds annually were not designated as hazardous substances if they had low probabilities of spillage. For example, substances with usages limited to research, medicinals, food additives, analytical reagents or unknown uses are not further considered for designation.

Pesticides were listed as hazardous substances regardless of their production volume because pesticides are distributed throughout the environment intentionally and EPA believes them "to have a high probability of discharge to the water."[12]

EPA also considered the selling price of a candidate substance to assess discharge potential. Available evidence indicates that substances with relatively high selling prices have smaller discharge frequencies, since more expensive chemicals are generally packaged and shipped in smaller quantities and with greater precautions. EPA maintains that the additional safeguards in the manufacture, handling, and processing of substances with high commercial market values minimize the possibilities of spillage.[13] Thus, only candidate substances with relatively low market prices are designated as hazardous substances.

Substances considered by EPA as candidate substances but not designated because they had low potentials for discharge are listed in Exhibit 2-17. They were not designated because of one or more of the following factors:

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[11] This discussion is derived from the Preamble to the Proposed Rule for the Designation of Hazardous Substances: 40 CFR 116. (40 FR 59964, December 30, 1975).

[12] 40 FR 59964 (December 30, 1975).

[13] Ibid.

EXHIBIT 2-17

MATERIALS DELETED BECAUSE OF LOW POTENTIAL FOR DISCHARGE

Ammonium Ferrocyanide
Ammonium Formate
Ammonium Gluconate
Ammonium Molybdate
Antimony Triiodide
Arsenic Tribromide
Arsenic Trifluoride
Arsenic Triiodide
Beryllium Hydroxide
Beryllium Phosphate
Beryllium Sulfate
Brucine
Cadmium Fluoborate
Cadmium Nitrate
Cadmium Sulfate
Catechol
Chromous Carbonate
Chromous Oxalate
Cobaltous Acetate
Cobaltous Chloride
Cobaltous Citrate
Cobaltous Iodide
Cobaltous Nitrate
Cobaltous Perchlorate
Cobaltous Succinate
Cobaltous Sulfate
Cupric Acetylacetonate
Cupric Bromide
Cupric Gluconate
Cuprous Iodide
Ferric Glycerophosphate
Ferric Phosphate
Ferrous Oxalate
Hydroquinone
Lead Bromide
Lithium Fluoride
Mercuric Ammonium Chloride
Mercuric Bromide
Mercuric Chloride
Mercuric Iodide
Mercuric Oxide
Mercurous Chloride
Mercurous Iodide
Molybdic Trioxide
Nickel Acetate
Nickel Bromide
Nickel Fluoride
Nickel Iodide
Nickel Perchlorate
Phosphorous Pentafluoride
Pyrogallic Acid
Selenic Acid
Selenium Oxychloride
Tannic Acid
Vanadium Oxytrichloride
Zinc Ammonium Sulfate
Zinc Permanganate
Zinc Propionate
Zirconium Ammonium Fluoride

Source: 40 FR 59965, December 30, 1975.

(1) No history of spill discharge,
(2) Low production quantity,
(3) Limited commercial use and distribution, and
(4) High value of the substance.[14]

Three substances proposed as hazardous substances were deleted by EPA in the final rulemaking.[15] The substances and reasons for deletion are:

Antimony Pentafluoride	Low potential for discharge (low production quantity and limited commercial use and distribution).
Zinc Sulfate Monohydrate	Redundant designation (listing of zinc sulfate includes monohydrate).
Adiponitrile	Does not meet Aquatic Animal Toxicity Requirements

EPA also deleted 21 substances in the final rulemaking because their usages are limited to research, medicinals, food additives, or analytical reagents. As discussed earlier, EPA considers chemicals with such usages to have low probabilities of spillage.

Chemicals with Limited Use

Ammonium Hypophosphite
Arsenic Acid
Chromyl Chloride
Cobaltous Fluoride
Cupric Formate
Cupric Glycinate
Cupric Lactate
Cupric Subacetate
Cuprous Bromide
Hydroxylamine
Lead Tetraacetate
Lead Thiosulfate
Lead Tungstate
Lithium Bichromate
Mercuric Acetate
Nickel Formate
Stannous Fluoride
Uranium Peroxide
Uranyl Sulfate
Zinc Bichromate
Zinc Potassium Chromate

Twelve substances were deleted from the proposed list because they were determined by EPA to be "not sufficiently toxic to meet the criteria:"[16]

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[14] 40 FR 59965 (December 30, 1975).

[15] Proposed in 40 FR 58870-6 (December 30, 1975).

[16] 43 FR 10479 (March 13, 1978).

Not Sufficiently Toxic

Aluminum Fluoride
Ammonium Iodide
Ammonium Bromide
Ammonium Nitrate
Ammonium Pentaborate
Ammonium Persulfate
Propyl Alcohol
Sodium Phosphate, Monobasic
Sodium Sulfide
Zirconium Acetate
Zirconium Oxychloride

On November 13, 1979, EPA deleted calcium oxide and calcium hydroxide (lime) from the list of hazardous substances. This action resulted from a Mississippi Lime Company petition for EPA to reconsider the designation of lime on the basis that:

(1) Lime discharges in the past have not resulted in environmental damage;

(2) Lime has beneficial uses; and

(3) Lime's chemistry and its reaction with water preclude the acutely toxic efects.

EPA decided that factors (1) and (2) were irrelevant to the designation of subtances as hazardous. The Clean Water Act does not require consideration of past environmental damage; moreover, since there were no reporting requirements for discharges of hazardous subtances in the past, there was no reason to assume that a substance had not at one time been discharged and resulted in environmental damage. EPA disregarded factor (2) because all chemicals produced commercially, presumably, have beneficial uses.

Upon consideration of factor (3), EPA deleted calcium hydroxide and calcium oxide from 40 CFR 116. EPA noted that lime is a dry bulk solid which forms a gel-like cover when exposed to water. The cover protects most of the lime from reaction with water. Furthermore, the small amount of lime which does react with water forms calcium carbonate (limestone) which is toxic to fish only at concentrations much greater than 500 mg/l (the cut-off concentration for aquatic animal toxicity). On this basis, EPA concluded that calcium hydroxide and calcium oxide do not meet the toxicological selection criteria, and hence, do not present an "imminent and substantial danger" to the environment when discharged.

PROPOSAL TO EXPAND SELECTION CRITERIA TO INCLUDE CARCINOGENIC EFFECTS

EPA recently proposed to expand the selection criteria for designating hazardous substances to include carcinogenic effects on humans.[17] Under this proposal, EPA would designate as "hazardous substances" those elements and compounds which are known or suspected to cause cancer in humans.

The proposed designation of carcinogens as hazardous substances follows a two-tiered process, which is similar to the general method for designation discussed previously. The primary difference is that rather than assessing chemicals according to short-term toxicological selection criteria, they are evaluated according to their carcinogenic (e.g., long-term) potential.

The designation procedure begins with EPA's Carcinogen Assessment Group (CAG) making a qualitative judgment of a chemical's human carcinogenic potential. In order to make such a judgment, the CAG considers data including epidemiological evidence, animal bioassay experimental evidence, and suggestive evidence (studies of chemical structure and short-term tests). The CAG evaluates the quality of data supporting human carcinogenicity according to the following gradient:[18]

- Best Evidence of Human Carcinogenicity--Positive epidemiological studies and confirmatory animal tests.
- Substantial Evidence of Human Carcinogenicity--Animal bioassay tests demonstrating the induction of malignant tumors or the induction of benign tumors that are generally recognized as early stages of malignancies, in one or more species.
- Suggestive Evidence of Human Carcinogenicity--Animal bioassay tests demonstrating the induction of non-life-shortening benign tumors and also positive results in indirect tests of tumorigenic activity (e.g., mutagenicity), in vitro cell transformation, and initiation-promotion skin tests in mice.

Compounds which demonstrate best evidence or substantial evidence of human carcinogenicity as defined above are included in the list of proposed carcinogens.

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[17] 45 FR 46094 (July 9, 1980).

[18] See the Proposed Amendment to Expanded Selection Criteria. 45 FR 46094 (July 9, 1980).

Proposed carcinogens are screened further on the basis of discharge potential. Substances which meet the discharge potential criteria described below are eliminated from consideration as hazardous substances:

(1) the substance has never been produced commercially; or

(2) the substance is used only as a laboratory reagent, medicinal, or specific food additive; or

(3) the substance is not produced except as a by-product of biological activity (such as aflatoxins); or

(4) the substance is not an element or compound, as required by law.[19] [Examples of such substances are soots and tars, which are known to be carcinogenic, but are not specific elements or compounds.]

The general discharge potential criteria (described earlier in this paper) which focused EPA's regulatory actions on chemicals with large annual production levels and low market prices are not applicable to the designation of carcinogens. Since the time the general criteria were established, EPA has evaluated for possible designation as hazardous substances many substances produced in large volumes and inexpensively. EPA is now able to consider substances with lower production volumes and higher costs. The new criteria were established accordingly.

In summary, a chemical becomes a candidate for proposed designation as a hazardous substance on the basis of carcinogenicity if:

(1) EPA's Carcinogen Assessment Group qualitatively determines that the chemical has carcinogenic potential, and

(2) there exists a reasonable potential for discharge.

EPA's proposal to expand the selection criteria also proposes to amend 40 CFR §116 by adding to the list of hazardous substances. The 14 substances listed in Exhibit 2-18 were proposed for designation on the basis of carcinogenicity.

In addition to those listed in Exhibit 2-18, EPA's Carcinogenic Assessment Group originally identified 12 other substances as having carcinogenic potential. The 12 chemicals listed in Exhibit 2-19 were

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[19] 45 FR 46095, July 9, 1980.

Exhibit 2-18

CARCINOGENS PROPOSED AS HAZARDOUS SUBSTANCES

Common Name	Synonyms or isomers
Benzidine	(1,1-Biphenyl)-4,4'Diamine; p-Diaminodiphenyl; Biphenyl; 4,4-Diamino-; 4-4'-Biphenyldiamine, 4,4'-Diaminobiphenyl.
Bis(2-chloroethyl)ether	Bis(beta-chloroethyl)ether, 1-chloro-2(beta-chloroethyoxy)ethane, 2,2'-dichlorodiethyl ether, beta, beta-dichloroethyl ether; di-2-chloroethyl ether; di-(beta-chloroethyl) ether, dichloroethyl oxide; sym-dichloroethyl ether, dichloroether, DCEE
Dibutylnitrosamine	n-Nitrosodibutylamine n-Nitrosodi-n-butylamine Nitrosodibutylamine; DBNA
Dichlorobenzidine	4,4'-Diamino-3,3'-Dichlorobiphenyl; 3,3'-Dichlorobenzidine; DCB
Diethyinitrosamine	N-Nitrosodiethylamine; Diethylamine; N-Nitroso-diethylnitrosamine; N-N-Diethylnitrosamine; DEN; DENA; DANA
N-Nitrosodimethylamine	Dimethylnitrosamine; Dimethylamine; N-Nitroso-dimethylnitrosamine, N-N-Dimethylnitrosamine; DMN, DMNA
Diphenylhydrazine	1,2-Diphenylhydrazine
Hexachlorobenzene	Perchlorobenzene
Hexachlorobutadiene	Perchlorobutadiene; Hexachloro-1,3-butadiene; HCBD

Exhibit 2-18

CARCINOGENS PROPOSED AS HAZARDOUS SUBSTANCES
(Continued)

Common Name	Synonyms or isomers
Hexachlorocyclohexane	alpha: alpha-benzene hexachloride; alpha-HCH; 1,2,3,4,5,6-hexachloroalpha-cyclohexane alpha-hexachlorocyclohexane; 1,2,3,4,5,6-hexachlorocyclohexane; alpha-isomer, alpha-lindane beta: *trans*-alpha-benzene hexachloride; beta-benzene hexachloride; beta-BHC; beta-hexachlorocyclohexane; beta-1,2,3,4,5,6-hexachlorocyclohexane; 1,2,3,4,5,6-hexachlorocyclohexane; beta-isomer,beta-lindane
Hexachloroethane	Carbon trichloride; Perchloroethane; Carbon hexa-chloride; Ethane hexachloride
1,1,2,2-Tetrachloroethane	Tetrachloroethane, Acetylene tetrachloride; sym-Tetrachloroethane
Tetrachloroethylene	Ethylene tetrachloride; Perchloroethylene
1,1,2-Trichloroethane	beta-Trichloroethane; Vinyl trichloride

Source: 45 FR 46097, July 9, 1980.

Exhibit 2-19

CARCINOGENS NOT MEETING DISCHARGE POTENTIAL CRITERIA[a/]

Arsenic
Beryllium
Cadmium
Chromium
bis-Chloromethylether
Vinyl Chloride
Polynuclear Aromatic Hydrocarbons
N-Nitrosotyrolodine
Tetrachlorodioxin
- alpha isomer Hexachlorocyclohexane
- beta isomer Hexachlorocyclohexane
- gamma isomer Hexachlorocyclohexane

[a/] This list was obtained from EPA's Marine Activities Branch.

eliminated from consideration as candidates for designation because they did not meet the discharge potential criteria.

EPA plans to evaluate for possible designation other carcinogens identified in RCRA Section 3001 regulations (Identification and Listing of Hazardous Waste).[20]

EPA initially considered expanding the selection criteria and the list of hazardous substances to include substances which are carcinogenic, mutagenic, teratogenic, radioactive, and which bioaccumulate in animal tissue to cause chronic toxic effects.[21] However, only criteria for potentially carcinogenic compounds were formally proposed by EPA. The Agency deferred consideration of designating substances on the basis of other factors (e.g., mutagenicity, teratogenicity) until a later date, because of inadequate information concerning:

(1) the appropriate basis for designating these substances;

(2) the bioaccumulation factor (i.e., ratio of a substance's concentration in animal tissue to that in the animal's environment) which is appropriate;

(3) how radioactive properties should be considered; and

(4) how these substances should be defined.[22]

DETERMINATION OF REPORTABLE QUANTITIES

The regulations authorized by Section 311(b)(4),[23] 40 CFR 117, establish reportable quantities for all designated hazardous substances, describe requirements for notification in the event of a discharge, and prescribe penalty provisions. This analysis focuses on the factors considered by EPA in determining the quantities of designated hazardous substances which activate the reporting and penalty provisions. This issue is important to the designation matter, since these regulations apply to designated substances only if the reportable quantities are exceeded.

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[20] Ibid.

[21] Advance Notice of Proposed Rulemaking, Proposed Expansion of Criteria for Designation. 44 FR 10270 (February 16, 1979).

[22] Ibid.

[23] The Clean Water Act, Section 311(b)(4), requires the EPA to determine "those quantities of . . . any hazardous substances the discharge of which may be harmful to the public health or welfare of the United States, including but not limited to fish, shellfish, wildlife, and public and private property, shorelines, and beaches" (emphasis added). These are termed reportable quantities.

First, the methodology EPA employs to determine reportable quantities is described. Both the methodology for determining reportable quantities on the basis of acute aquatic toxicity and the methodology based on carcinogencity are examined. Then the relationships between Part 117 and other hazardous substances regulations (including Department of Transportation regulations) are reviewed. The rationale under which discharges are regulated under Part 117 is explained.

Method for Determining Reportable Quantities

Thus far, EPA has relied primarily on the acute aquatic toxicity of designated substances to derive their reportable quantities.[24] The other selection criteria adopted in 40 CFR 116, (the acute toxic effects to mammals and plants) have not been employed by the Agency, as yet, to designate hazardous substances. EPA will establish a methodology based on acute toxicity to mammals or plants once these criteria are utilized to designate hazardous substances.[25] In the meantime, the method for determining reportable quantities is based solely on acute aquatic toxicity.

The procedure devised by EPA to determine reportable quantities begins by placing substances in one of five categories on the basis of acute toxicity to aquatic organisms. These five categories are:

Category X: Substances which are most highly toxic to aquatic life.

Category A: Substances which are highly toxic to aquatic life.

Category B: Substances which are moderately toxic to aquatic life.

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[24] EPA has proposed a methodology for determining reportable quantities for substances on the basis of carcinogenicity (45 FR 46097, July 9, 1980). EPA is reviewing public comment on the proposal and, as of January 1, 1980, no final rule had been promulgated.

[25] Preamble to the Final Rulemaking of Part 118--Determination of Harmful Quantities for Hazardous Substances. 43 FR 10490 (March 13, 1978).

Category C: Substances which are slightly toxic to aquatic life.

Category D: Substances which are practically non-toxic to aquatic life.

The mean lethal toxicity levels associated with each category are listed in Exhibit 2-20 under the column entitled "Toxicity Range." To date, EPA has relied exclusively on the 96-hour LC50 toxicity test (i.e., the concentration likely to kill 50 percent of a fish population in 96 hours) to assign substances to particular categories.

EPA defined the reportable quantity for members of Category X as the size of the smallest common commercial container--one pound (or .454 kilograms). Other categories were thereafter assigned reportable quantities on a proportional basis. For example, Category A has a toxicity range of 10 times Category X's toxicity range, so the reportable quantity for Category A is set at 10 times Category X's reportable quantity (i.e., 10 pounds).

Exhibit 2-20 illustrates the toxicity range and the associated reportable quantity for each Category.

The regulations apply only to discharges of reportable quantities "in any 24-hour period". Neither Section 311 nor its legislative history suggest a time limit for applicability of reportable quantities. Thus, EPA set the time limit of 24 hours to control short-term nonroutine discharges of hazardous substances.[26]

No Consideration of Water Body Characteristics. It is important to note that the reportable quantity for each hazardous substance is constant for all water bodies covered by the regulations. Although the characteristics of the receiving water body such as the type, size, flow, salinity, temperature, hardness, alkalinity and biological populations effect the toxicity of a particular hazardous substance, these factors are not considered by EPA when determining reportable quantities. The reasons for this are both statutory and administrative.

Section 311 of the Clean Water Act requires that the determination of reportable quantities be made prior to the actual discharge of a hazardous substance. Senator Muskie, during Congressional debate on the amendments to the Clean Water Act, declared that:

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[26] 44 FR 50775 (August 29, 1979).

Exhibit 2-20

EPA CATEGORIES FOR REPORTABLE QUANTITY DETERMINATION

Category	Toxicity Range	Reportable Quantity Pounds (Kilograms)
X	LC50[a] $\leq$ 0.1ppm	1.0 (0.454)
A	0.1ppm $\leq$ LC50 $\leq$ 1ppm	10 (4.54)
B	1ppm $\leq$ LC50 $\leq$ 10ppm	100 (45.4)
C	10ppm $\leq$ LC50 $\leq$ 100ppm	1,000 (454)
D	100ppm $\leq$ LC50 $\leq$ 500ppm	5,000 (2,270)

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[a] LC50 values mean the concentration of material which is lethal to one-half of the test population of aquatic animals upon continuous exposure for 96 hours or less.

Source: 43 FR 10492 (March 13, 1978).

> "These (determinations of removability, reportable quantity, and rate of penalty) are nationally applicable, before-the-fact decisions and are not expected to reflect the myriad of actual circumstances that may occur."[27]

In order for determinations of reportable quantities to be made before discharge incidents occur, the specific characteristics of the water receiving the discharge can not be considered.

The legislative history and the statutory language indicate that determinations of reportable quantities are not to be based on assessments of actual harm in the variety of circumstances in which hazardous substances might be discharged. Section 311(b)(4) applies to hazardous substances which "may be harmful"; the statute does not require EPA to demonstrate and predict those quantities of substances which, under various circumstances, are harmful. Rather, Congress expects the reportable quantities to be "rational generalized predictions"[28] of those quantities which may be harmful. Congress intended that the determination (of reportable quantities) be based on "chemical and toxic properties of the substance itself, not the circumstances surrounding its release."[29]

Other reasons for not considering the characteristics of the receiving water body when establishing reportable quantities are administrative. First, consideration of all the potentially influencing factors would be administratively impossible for the Agency: "The number of potentially influencing factors and their possible combinations would render any predictive model based on them entirely too cumbersome for regulatory application."[30] Second, if characteristics of the receiving water body are considered when determining reportable quantities, dischargers would be responsible for differentiating between various types of water bodies. This is not always an easy task; frequently, boundaries and types of water bodies are not clearly defined. A regulatory approach allowing different reportable quantities for different types of water would "place an unfair burden on dischargers."[31] Dischargers would face criminal penalties for failure to immediately report a discharge, even though there would be considerable uncertainty as to what constitutes a violation. Third, this regulation is intended to establish prompt notification for discharges of hazardous substances. If dischargers are required to evaluate the type of receiving water body, the regulatory goal of prompt reporting may not be achieved.

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[27] Congressional Record at S19653 (December 15, 1977).

[28] See Preamble to the Proposed Rulemaking of Part 117--Determination of Reportable Quantities, 44 FR 10271, February 16, 1979.

[29] Ibid.

[30] Preamble to the Final Rulemaking of Part 118--Determination of Harmful Quantities for Hazardous Substances. 43 FR 10491 (March 13, 1978).

[31] Ibid.

Concentration and Mixtures. The proposed approach for determining reportable quantities for mixtures or solutions was to assume that damages caused by individual constituents were additive. Proportions of individual elements or compounds in a discharged mixture or solution were added to determine if reportable quantities were exceeded.[32] For example, a discharge of a mixture containing 70 percent of a reportable quantity of substance A and 60% of a reportable quantity of substance B, would be subject to the proposed rule because .70 + .60 = 1.30 which is greater than one.

Prior to the Final Rulemaking, EPA reevaluated the assumption that toxic properties of different substances can be considered additive. The Agency concluded that the additive assumption was "not valid for all combinations of designated hazardous substances."[33] Furthermore, EPA viewed the calculations for mixtures and solutions as "unnecessarily difficult".[34] Thus, the regulations were revised so that mention of mixtures and solutions in Part 117.3 was removed. As a result, discharges of mixtures and solutions are subject to the regulations only where a component hazardous substance is discharged in a quantity equal to or greater than its reportable quantity, no matter what the concentration.

Method for Determining Reportable Quantities for Carcinogens

EPA has proposed to utilize a different method of determining reportable quantities for chemicals likely to be carcinogenic in humans from that utilized in establishing reportable quantities for chemicals on the basis of aquatic toxicity. EPA's rationale for establishing a separate method was that carcinogens pose different relative risks than substances which demonstrate acute aquatic toxicity. For example, the procedure based on aquatic toxicity would not designate as reportable a concentration of a substance likely to kill one fish out of a population of 2,000 fish. However, a substance likely to cause cancer in one person out of 2,000 exposed should be considered harmful to public health and welfare; EPA proposed a method of assessing carcinogenic risks to reflect the relative risk (45 FR 46097).

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[32] 44 FR 10271 (February 16, 1979).

[33] Preamble to the Final Rulemaking of Part 117--Determination of Reportable Quantities, 44 FR 50767 (August 29, 1979).

[34] Ibid.

This section of the paper summarizes the methodology and rationale that may be used by EPA to determine reportable quantities for potentially carcinogenic chemicals.[15] Appendix A reviews the details of the methodology.

First, the Agency would establish "a lifetime cancer risk level that is considered sufficiently hazardous to require reporting." This lifetime risk level was set at one in one million (10^{-6}). No reasons for selecting 10^{-6} as the level were provided.

Second, the Agency would construct a "spill analysis model" to describe the relationship between amounts discharged and risk levels. This model does not predict the risk of harm for all potential discharge situations. Rather, it assumes the discharge of a carcinogen to a water body under worst case conditions. Such an approach is permissible according to the statutory language and legislative history of Section 311, since the spill analysis model ultimately determines quantities of hazardous substances which may be harmful.

Using the spill analysis model, EPA derived the formula (see Appendix A for details):

$$n = 9.85/B$$

which gives the number of pounds of material, n, having carcinogenic potency, B, which would result in a lifetime cancer risk of 10^{-6}.

EPA grouped the designated carcinogens into five categories on the basis of potential harm. These categories and respective reportable quantities are the same as those used by EPA to group the other designated hazardous substances. They are listed below in Exhibit 2-21.

List of Reportable Quantities

Exhibit 2-15, the List of Hazardous Substances, presented earlier, shows the reportable quantities for each hazardous substance listed in 40 CFR 116. The first number under the column headed "RQ" is the reportable quantity in pounds. The number in parentheses is the metric equivalent in kilograms. The column labeled "Category" lists the code letters "X", "A", "B", "C", and "D" corresponding to the reportable quantities of 1, 10, 100, 1000, and 5000 pounds, respectively.

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[15] This description of EPA's approach is taken from the Preamble to the Proposed Rule: Determination of Reportable Quantities for Hazardous Substances, 45 FR 46097 (July 9, 1980).

EXHIBIT 2-21

EPA CATEGORIES FOR REPORTABLE QUANTITIES DETERMINATIONS FOR CARCINOGENS

Pounds of Substance Discharged Yielding A Risk of 10-6	Category	Reportable Quantity (Pounds)
Less than 1	X	1
1 to 10	A	10
10 to 100	B	100
100 to 1,000	C	1,000
1,000 to 5,000	D	5,000

Source: 45 FR 46098, July 9, 1980 (proposed rule).

Any 24-hour discharge greater than or equal to the reportable quantity is subject to the notification procedures and penalties described in 40 CFR Parts 117.21 and 117.22. Discharges covered by these regulations include hazardous substances which spill, seep, leak or wash into waters or adjoining shorelines. There are exceptions to these regulations which are described, in detail, later in this paper.

The 14 substances proposed for designation on the basis of carcinogenicity, and their reportable quantities are listed in Exhibit 2-22. Additionally, EPA proposed to lower the reportable quantities for six substances that are already on the existing hazardous substances list in 40 CFR 116. EPA's rationale for this is that the reportable quantities based on carcinogenicity are lower than those based on aquatic toxicity. In order to prevent either environmental or human risk, the Agency believes that the smaller of the two reportable quantities should be controlling. The proposed changes for reportable quantity values also are presented in Exhibit 2-22.

EXCLUSIONS FROM COVERAGE

40 CFR 117 covers any 24-hour discharge greater than or equal to the reportable quantity except for discharges excluded from Section 311 coverage. These exclusions include:

(1) discharges from facilities with National Pollutant Discharge Elimination System (NPDES) permits, and

(2) discharges from Publicly-Owned Treatment Works.

Exhibit 2-23 summarizes the exceptions to 40 CFR 117.

EXHIBIT 2-22

PROPOSED REPORTABLE QUANTITIES FOR HAZARDOUS SUBSTANCES DESIGNATED ON THE BASIS OF CARCINOGENICITY

Chemical	Category	RQ in Pounds	(Kilograms)
Acrylonitrile[a]	A	10	(4.54)
Benzidine	A	10	(4.54)
bis-(2-chloroethyl)ether	B	100	(45.4)
Carbon tetrachloride[a]	C	1,000	(454)
Chloroform[a]	B	100	(45.4)
Dibutylnitrosamine	X	1	(0.454)
Dichlorobenzidine	A	10	(4.54)
Diethylnitrosamine	X	1	(0.454)
Dimethylnitrosamine	X	1	(0.454)
Dinitrotoluene[a]	B	100	(45.4)
Diphenylhydrazine	B	100	(45.4)
Ethylene dichloride[a]	C	1,000	(454)
Hexachlorobenzene	A	10	(4.54)
Hexachlorobutadiene	C	1,000	(454)
Hexachlorocyclohexane (except gamma-HCH)	A	10	(4.54)
Hexachloroethane	C	1,000	(454)
1,1,2,2-Tetrachloroethane	B	100	(45.4)
Tetrachloroethylene	C	1,000	(454)
1,1,2-Trichloroethane	B	100	(45.4)
Vinylidene chloride[a]	B	100	(45.4)

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[a] The chemical is on the existing hazardous substances list in 40 CFR 116 and has a reportable quantity based on acute toxicity recorded in 40 CFR 117. EPA proposed to lower the reportable quantity on the basis of carcinogenicity.

Source: 45 FR 46099, July 9, 1980 (proposed rule).

EXHIBIT 2-23

EXCEPTIONS TO 40 CFR 117 REGULATIONS

Regulation or Source	Specific Exception
Marine Protection, Research and Sanctuaries Act of 1972 (33 USC 1401 *et seq.*)	Discharges made in compliance with a permit issued under the Act.
State and Local Safe Drinking Water Regulations	Discharges made in compliance with approved water treatment plant operations.
Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 USC 136 *et seq.*)	Allowable discharges of a pesticide registered under section 3 or section 24. Discharges made under an experimental use permit issued under section 5. Discharges made pursuant to an exemption under section 18.
Resource Conservation and Recovery Act (90 Stat. 2795; 42 USC 6901)	Discharges made in compliance with the regulations issued under Section 3004. Discharges made in compliance with permit conditions under Section 3005.
National Oil and Hazardous Substances Pollution Plan (40 CFR 1510)	Discharges made in compliance with instructions of the On-Scene Coordinator.
Pollution by Oil and Hazardous Substances (33 CFR 153.10)	Discharges made in compliance with instructions of the On-Scene Coordinator.
Clean Water Act, Section 311(f)(1)	Discharges caused solely by an Act of God, an Act of War, negligence on the part of the U.S. Government, or an act or omission of a third party without regard to whether any such act or omission was or was not negligent, or any combination of these clauses.

EXHIBIT 2-23

EXCEPTIONS TO 40 CFR 117 REGULATIONS
(continued)

Regulation or Source	Specific Exception
Clean Water Act	Discharges made in compliance with a permit issued under Section 404(a). Discharges exempt from requirements under Section 404(f) or (404)(r). Discharges made in compliance with a permit issued under Section 402. Other discharges made under Section 402, as specified in 117.12. Discharges excluded from Part 117.12 and from a permitted source.
Publicly-Owned Treatment Works (POTW)	Discharges made to a POTW from industrial facilities Discharges made to a POTW from a mobile source which has been permitted by the POTW to discharge that quantity. Discharges made by POTWs of substances received as influent.
Providing Inert Gas to Cargo Tanks of a Vessel	Discharges made from a properly functioning inert gas system.
Demonstration Projects	Discharges approved by EPA on a case-by-case basis.

Source: 40 CFR Parts 117.11, 117.12, 117.13 and 117.14.

The various exceptions allow potential opportunities for gaps in coverage of Section 311 designated hazardous substances. A discharge of a hazardous substance excluded from Section 311 coverage may exceed the Part 117 reportable quantity for that substance, and yet, not be controlled under other regulatory or statutory provisions. For example, there are no reportable quantities for discharges of hazardous substances from facilities with NPDES permits, but such discharges are excluded from 40 CFR 117. This allows the possibility of discharges which exceed Part 117 reportable quantities and "may be harmful".

Discharges From Facilities With National Pollutant Discharge Elimination System (NPDES) Permits

At the time EPA proposed rules for determining reportable quantities, the Agency was unclear whether and to what extent discharges from facilities with NPDES (Section 402) permits were subject to the provisions of Section 311. The November 2, 1978 amendment to the Clean Water Act (Public Law 95-576) clarified this issue by distinguishing between discharges subject to Section 311 and those subject to Section 402 on the basis of the source and circumstances surrounding the discharge. Under the Amendment, discharges from permitted point sources associated with manufacturing and treatment would be regulated under Sections 402 and 309 of the Clean Water Act, whereas spill situations would be subject to Section 311 regulations.

Specifically, the three cases excluded from Section 311 coverage by the 1978 amendment to the Act are:

(1) discharges in compliance with a permit under Section 402 of the Act;

(2) discharges resulting from circumstances identified and reviewed and made a part of the public record with respect to a permit issued or modified under Section 402 of the Act, and subject to a condition in such permit; and

(3) continuous or anticipated intermittent discharges from a point source, identified in a permit or a permit application under Section 402 of the Act, which are caused by events occurring within the scope of relevant operating or treatment systems.[16]

Discharges excluded from Section 311 coverage and in compliance with a permit under Section 402 are subject to controls similar to those found in 40 CFR 117. Comparable reporting requirements, civil penalty liability, and cost of clean-up liability apply to discharges under both sections. For this reason, EPA decided that the NPDES regulations would control chronic discharges of Section 311 designated hazardous substances adequately.

The second exclusion applies to discharges of hazardous substances from Section 402 permitted sources which result from circumstances such as chronic process waste discharges or tank ruptures. The applicable permit must include conditions to prevent or contain discharges, or eliminate or abate the substance prior to discharge (for example, a holding pond to contain materials discharged from a tank rupture) and a system to treat the contained substances over time).[37]

On-site industrial spills such as truck or rail accidents, large-scale failures or ruptures of containers or vessels would not be excluded from coverage under Section 311. However, if such on-site spills were processed through a treatment system capable of eliminating or abating such spills, and were subject to a permit condition, such discharges would be regulated under Section 402. If a discharge of a hazardous substance did not pass through a waste treatment system or was not otherwise treated in any way, Section 311 would apply.[38]

The third exclusion concerns periodic upsets and failures of treatment systems resulting in continuous or intermittent discharges. Examples are upsets or failures which result from a control problem, an operator error (not including error causing classic spills, such as accidental tank ruptures, since such events do not occur within the scope of operation or treatment systems), a system failure or malfunction, an equipment or system startup or shutdown, an equipment wash, or a production schedule change, provided that such upset or failure is not caused by an on-site spill of a hazardous substance.[39] Upsets occurring from improperly maintained equipment are not excluded from Section 311 coverage.

Exclusion three also applies to discharges resulting from the contamination of noncontact cooling water or storm water, provided that the water is not contaminated by an on-site spill of a hazardous substance.[40]

Discharges From Publicly-Owned Treatment Works

Discharges of hazardous substances through Publicly-Owned Treatment Works (POTWs) may reach navigable waters and, thus, be subject to regulation under Section 311. Such discharges can result from accidental spills of materials

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[36] 40 CFR 117.12(a).

[37] 44 CFR 10273, February 16, 1979.

[38] 40 CFR 50769 (August 29, 1979).

[39] 40 CFR 117.12(d)(2)(iii).

[40] 40 CFR 117.12(d)(2)(i).

into sewer lines, intentional dumps into manholes, or through routine discharges made by facilities which use POTWs to dispose of process wastes.[41] EPA has tried to clarify the difference between chronic discharges to POTWs which should be regulated under Sections 307(b), (c) and 309,[42] and spills to POTWs which should be regulated under Section 311.[43]

EPA suggested two possible options for making this differentiation in the February 1979 Proposed Rulemaking and solicited public comments. In the Final Rulemaking for the Determination of Reportable Quantities, EPA rejected both options and reserved the regulation of discharges from industrial facilities to POTWs until a later date. The Agency's reasons for reserving regulation were:

(1) The complexity of the issues,

(2) The uncertainty about the best way to distinguish chronic discharges from spills, and

(3) The potential impact of any decision on the thousands of facilities which regularly discharge hazardous substances to POTWs.[44]

A POTW may not be aware of a hazardous substance received as influent at the treatment works prior to a discharge; thus, the role and responsibility of a POTW in this case is difficult to define. EPA has concluded that "it is unreasonable to hold the POTW liable for discharges from users, or under circumstances which it is unaware of, or unable to control."[45] The final rulemaking for 40 CFR 117 reserved the regulation of discharges of hazardous substances received as influent by a POTW (Part 117.13(a)). This means that such discharges from POTWs are meanwhile exempted from Part 117 regulations.

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[41] 44 FR 10271 (February 16, 1979).

[42] Section 307(b) authorizes EPA to promulgate pretreatment standards for pollutants introduced into publicly owned treatment works. Section 307(c) authorizes EPA to promulgate pretreatment standards for pollutants discharged to POTWs from new sources subject to standards of performance under Section 306 of the Clean Water Act. Section 309 describes procedural requirements for standards promulgated under the Clean Water Act.

[43] Proposed Rulemaking for Determination of Reportable Quantities, 44 FR 10271, February 16, 1979.

[44] 44 FR 50769, August 29, 1979.

[45] *Ibid*.

Discharges of designated hazardous substances to POTWs are subject to Part 117 regulations where a discharge of a reportable quantity is made to a sewer system from a truck, train, or other mobile source which has not "contracted with or otherwise received written permission from the owners or operators of the POTW to discharge that quantity."[46] For example, discharges to a sewer system by a waste hauler who contracts to discharge specified hazardous substances to the sewer would not be covered by 40 CFR 117. However, an illegal discharge or "midnight dump" as well as any accidental discharge by a mobile source to a POTW's sewer system would be subject to the applicable provisions of 40 CFR 117.[47]

EPA singled out mobile sources to be regulated separately from industrial facilities for these reasons:

(1) Mobile sources are not subject to NPDES permits, industry specific effluent limitations, or pretreatment standards.

(2) POTWs cannot design or operate the treatment works to assure that the discharge of unanticipated hazardous substances by a mobile source would not reach navigable waters.

(3) POTWs may not even know of the presence of a hazardous substance unless notified.

(4) In some cases, POTWs lack the authority to control discharges by mobile sources.

(5) Out-of-town carriers of intra and interstate commerce, unlike fixed facilities, may not be aware of the existence of local requirements for notification, pretreatment, or clean-up in the event of a spill to the sewers.

(6) Spills involving mobile sources are difficult to anticipate in advance and prevent.[48]

Section 311 does not give EPA the authority to require mobile sources who spill to POTWs to notify the POTW. Thus, Part 117 regulations require only that a mobile source notify the Coast Guard in the event of a discharge to a POTW.

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[46] 40 CFR 117.13(b).

[47] 44 FR 50770 (August 29, 1979).

[48] See 44 FR 50771 (August 29, 1977).

Spills During Transport

Part 117 regulations apply to discharges of hazardous substances from vessels, onshore facilities, and offshore facilities, unless the discharge is covered by the exceptions discussed earlier.[49] Section 311 (a)(10) defines "onshore facility" to include motor vehicles and rolling stock. Thus, the applicability of Part 117 regulations to the transportation of hazardous substances needs to be explored. In particular, the responsibilities of EPA and the Department of Transportation need to be clarified.

At the time of the final rulemaking for 40 CFR 117, EPA deferred the effective date of Part 117 regulations as they apply to discharges from common carriers including railroads and many trucks because:[50]

(1) At that time, common carriers were required by law to transport all shipments offered to them in accordance with applicable tariff requirements.

(2) There was no legal requirement for shippers to identify their cargoes as containing Section 311 designated hazardous substances.

Common carrier personnel had no means of determining when they were transporting substances subject to Part 117 regulations. Spills by common carriers could not be reported unless the personnel had previous knowledge of the presence of a hazardous substance in the cargo.

It is important to note that EPA requires private and contract carriers to follow Part 117 regulations. Shippers must identify any shipments containing hazardous substances if requested by a private or contract carrier. In addition, these types of carriers may refuse to transport Section 311 designated hazardous substances. Hence, private and contract carriers have the means to determine if they are transporting substances subject to Part 117 regulations, and if so, to abide by the regulations.

In order to clarify the responsibilities of the Environmental Protection Agency and the Department of Transportation, DOT promulgated a final rule specifically addressing the transportation of hazardous substances.51/ The rule, 49 CFR 171, applies to the transportation of hazardous substances in reportable quantities by rail car, aircraft, and vessel carriers, as well as interstate and intrastate motor vehicle carriers.

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[49] 40 CFR 117.21.

[50] 44 FR 50775, August 29, 1979.

[51] 45 FR 34560, May 22, 1980. See discussion in Volume 3, DOT Regulatory Review.

In the DOT regulations the term hazardous substance means "a quantity of a material offered for transportation in one package, or transport vehicle when the material is not packaged, that equals or exceeds the reportable quantity (RQ) specified for the material in EPA regulations at 40 CFR Parts 116 and 117."[52]

DOT adopted EPA's reportable quantity classifications because:[53]

- The risk involved from transporting hazardous materials includes the possibility of unintentional releases into or upon the navigable waters or adjoining shorelines.

- EPA has both the experience and the technical resources necessary to deal with the determination and designation of hazardous substances mandated by the Clean Water Act.

- If DOT did not take this action, EPA would be required to regulate the transportaton of those hazardous substances not covered by DOT regulations. This type of split in regulatory coverage would be inefficient.

The application of DOT's regulations to mixtures and solutions containing hazardous substances is illustrated by the inclusion of the following table in 40 CFR 171:

RQ Pounds	RQ Kilograms	Concentration by Weight	
		Percent	PPM
5,000	2,270	10	100,000
1,000	454	2	20,000
100	45.4	0.2	2,000
10	4.54	0.02	200
1	0.45	0.002	20

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[52] 49 CFR 171.8.

[53] See 44 FR 10677, February 22, 1979 and 45 FR 34569, May 22, 1980.

If the reportable quantity for a certain hazardous substance is 100 pounds, less than a 0.2 percent concentration by weight of that material in a mixture or solution would NOT be subject to DOT's regulations. Further, the 0.2 percent or greater concentration by weight of that material must be contained in one package to be subject to DOT's regulations.

Thus the DOT regulations are closely related, but not identical to the Part 117 regulations for discharges of hazardous substances.

Appendix A

PROPOSED METHODOLOGY FOR DETERMINING REPORTABLE QUANTITIES FOR CARCINOGENS

The worst case assumptions used in the spill analysis model are:

- the discharge is into a water supply impoundment at the beginning of the drawdown cycle during severe drought conditions;
- the impoundment serves a population of 10,000 persons;
- no other water supply is available;
- the impoundment has no other uses besides water supply;
- no treatment technology for removing the carcinogen is installed;
- the carcinogen mixes rapidly and completely at the beginning of the drawdown cycle;
- at least 75 percent of the water is withdrawn and used for water supply;
- eighty percent of the contaminant will enter the water supply system;
- the average daily water use per individual is 400 liters of which 0.5 percent is ingested; and
- the lifetime average daily dose, D, in units of milligrams/kilogram of body weight/day is: $D = (4 \times 10^{-7})\ n\ LW$, where n is the amount spilled, L is lifetime in days, W is body weight, and (4×10^{-7}) is the total dose of the contaminant received by each person.

The "one-hit" model of low-dose extrapolation estimates the cancer risk of a particular compound to humans. EPA expresses the model in terms of this equation:

$$P = BD = (4 \times 10^{-7})\ Bn/LW \qquad (1)$$

where B is the carcinogenic potency of the compound. The potency or "slope parameter" for each of the carcinogen's addressed in this rulemaking are displayed below. These potency figures were derived from linear extrapolations of dose-response data for each compound.

From equation (1), the amount of a chemical that produces a risk "P" is:

$$n = PLW/(4 \times 10^{-7})B \qquad (2)$$

EPA assumes that the parameters of this equation are $P = 10^{-6}$, $L = 25{,}500$ days (70 years), and $W = 70$ kilograms.

Hence, equation (2) is equivalent to this formula:

$$n = 9.85/B$$

which gives the number of pounds of material, n, having carcinogenic potency, B, which would result in a lifetime cancer risk of 10^{-6}.

CARCINOGENIC POTENCY FOR EACH CARCINOGEN
PROPOSED FOR DESIGNATION AS A HAZARDOUS SUBSTANCE[a/]

Carcinogen	Potency
Acrylonitrile	2.0
Benzidine	2.0
bis-(2-chloroethyl) ether	0.68
Carbon tetrachloride	0.0901
Chloroform	0.15
Dibutylnitrosamine	27
Dichlorobenzidine	1.9
1,2-Dichloroethane	0.048
1,1-Dichloroethylene	0.26
Diethylnitrosamine	38
Dimethylnitrosamine	13
Dinitrotoluene	0.42
Diphenylhydrazine	0.72
Hexachlorobenzene	2.5
Hexachlorobutadiene	0.049
Hexachlorocyclohexane	2.0
Hexachloroethane	0.015
1,1,2,2-Tetrachloroethane	0.16
Tetrachloroethylene	0.084
1,1,2-trichloroethane	0.12

Source: 45 FR 46098 (July 9, 1980).

THE SAFE DRINKING WATER ACT -- STATUTORY REVIEW

INTRODUCTION

In December of 1974, Congress approved an amendment to the Public Health Service Act authorizing a new section to cover public drinking water supplies. Title XIV, the Safe Drinking Water Act,[1] authorizes EPA to establish federal standards to protect public water systems from harmful contaminants, and establishes a joint Federal-State system for ensuring compliance with the standards and for protection of underground sources of water. The purpose of the legislation was to assure that public water supplies meet minimum standards for protection of public health.

At that time, there was a lack of federal authority to deal with contaminants in drinking water. Under the original Public Health Service Act, EPA was authorized to regulate contaminants only to prevent the spread of communicable diseases, and then only applied to interstate carriers. A 1970 study by HEW had shown a large(36%) percentage of drinking water was contaminated with harmful chemicals and bacteria, and exceeded the existing 1962 Public Health Service limits (42 CFR 70) which have since been superceded by EPA regulations. In addition, there was a lack of authority, techniques, and resources at the State and local level for enforcement of any standards that were available.[2]

Consequently, Congress expanded EPA's regulatory authority to include the establishment of drinking water standards. More specifically, the SDWA authorized EPA to promulgate:

- interim and revised primary drinking water regulations to control contaminants which "may have an adverse effect" on human health; where contaminant is defined as "any physical, chemical, biological or radiological substance or matter in water;" [Section 1401(6)]

- secondary drinking water regulations to provide guidelines to states for the control of certain contaminants in drinking water to protect the public welfare; and

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[1] PL 93-523, enacted by Congress December 3, 1974; signed by the President December 17, 1974; amended by PL 95-190, November 16, 1977; PL 96-63, September 6, 1979. See 42 U.S.C. §300f et. seq.

[2] House Report No. 93-1185, as reported in 1974 United States Code Congressional and Administrative News (USCCAN), p. 6461.

- regulations which set minimum requirements for state programs designed to control the underground injection of chemicals which may find their way into public drinking water supplies.

Each of these authorities will be reviewed following an overview of the statutory criteria.

NATIONAL INTERIM PRIMARY DRINKING WATER REGULATIONS

To meet its first, short-term goal, the Act directed EPA to promulgate "national interim primary drinking water regulations" (NIPDWRs) within nine months of the date of enactment in 1974. In setting such a stringent deadline, Congress' goal was to get a set of standards (or so-called "interim" regulations) enacted as quickly as possible, based on currently available information. As the Act was worded, these interim standards were to (1) specify "contaminants which, in the judgement of the Administrator, may have an adverse effect on the health of persons",[3] and (2) "protect health to the extent feasible, using technology, treatment techniques, and other means, which the Administrator determines are generally available (taking costs into consideration) on the date of enactment of this title."[4]

In setting these standards, EPA was to base its decisions on "epidemiological, toxicological, physiological, biochemical or statistical research or studies or extrapolations therefrom." Congress, however, did not want EPA to wait for harm to the public to occur--the preventive purpose of the legislation requires that the EPA Administrator make a reasoned and plausible judgment that a contaminant may have adverse health effects.[5] Congress anticipated that the interim regulations would be based on a review and update of U.S. Public Health Service drinking water standards.

The SDWA authorized EPA to control "contaminants" in drinking water by specifying either a maximum contaminant level (MCL) or treatment techniques sufficient to protect against "adverse effects on the health of persons" and to allow an "adequate margin of safety".[6] The decision to adopt an MCL over technology-based standards is to be made "if, in the judgment of the Administrator, it is economically and technologically feasible to ascertain the level of such contaminant in water in public water systems. . . "[7] In other words, MCLs are to be set for specific pollutants which can be detected, measured, and monitored in drinking water; treatment techniques should be used to control all other pollutants for which identification and measurement is not yet feasible.

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[3] Section 1401 (1)(B), (emphasis added).

[4] Section 1412(a)(2), (emphasis added).

[5] H. Report No. 93-1185, 1974 USCCAN p. 6463.

[6] Section 1412 (e)(2)(C).

[7] Section 1401 (1)(c)(i) and (ii), and Section 1401 (1)(B) (emphasis added).

REVISED PRIMARY DRINKING WATER REGULATIONS

The second phase of the strategy was to commence a concerted longer-term effort to gather additional data identifying the types and concentrations of pollutants found in drinking water supplies. These data were to be used to determine whether revisions were necessary for any or all of the interim standards and, if so, to provide the scientific information base needed to make such revisions. To carry out this data-gathering effort, the Act required EPA to arrange with the National Academy of Sciences (NAS) "to conduct a study to determine (A) the maximum contaminant levels which should be *recommended* . . . *in order to protect the health of persons from any known or anticipated health effects*, and (B) the existence of any contaminants "the levels of which in drinking water cannot be determined but which *may have an adverse effect on the health of persons*."[8] In developing proposals for recommended MCLs, NAS was required to "evaluate and explain (separately and in composite) the impact" of

> (1) The existence of groups or individuals in the population which are more susceptible to adverse effects than the normal healthy adult;
>
> (2) the exposure to contaminants in other media than drinking water (including exposures to food, in the ambient air, and in occupational settings) and the resulting body burden of contaminants;
>
> (3) synergistic effects resulting from exposure to or interaction by two or more contaminants; and
>
> (4) the contaminant exposure and body burden levels which alter physiological function or structure in a manner reasonably suspected of increasing the risk of illness.[9]

Congress intended the NAS proposed levels to represent goals based on health effects only, and did *not* intend them to consider what is technologically or economically feasible or reasonable.[10] Besides the special health considerations noted above, Congress wanted NAS to include an "adequate margin of safety" based on margins of safety currently used in regulating foods and drugs, pesticides, air and water pollution, etc., as well as potential health effects.[11] Results of the NAS study were to be reported to Congress within two years. Within ten days of the publication of the NAS report, EPA was required to publish in the *Federal Register* the list of contaminants identified by the report and the recommended MCLs.

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[8] Section 1412(a)(2) (emphasis added).

[9] Section 1412(e)(3). The phrase "reasonably suspected of increasing the risk" was not discussed in the Legislative History or defined in the statute.

[10] H. Report No.93-1185 1974 USCCAN p. 6472.

Within ninety days of this publication in the *Federal Register*, the EPA Administrator was required to propose *recommended maximum contaminant levels for each contaminant which, in his judgement based on the report, may have any adverse effect* on the *health of persons*. Each recommended maximum contaminant level must be set at a level, at which, in the Administrator's judgement based on such report, *no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety*. In addition, the Administrator shall, on the basis of the report, list any contaminants which cannot be measured in drinking water accurately enough to establish a recommended maximum contaminant level, and which may have any adverse effect on the health of persons. Based on available information, the Administrator may change recommended maximum levels or revise the list.[12]

Finally, within 180 days of the proposed regulations, the Administrator was to promulgate "such revised drinking water regulations with such modifications as he deems appropriate."[13] The MCL specified in a revised national primary water regulation was to be as close to the recommended maximum contaminant level established by the NAS recommendations *as is feasible*. A required treatment technique for a contaminant, for which a recommended maximum contaminant level has been established shall reduce such contaminants to a level which is *as close to the recommended* maximum contaminant level for such contaminant *as is feasible*. A required treatment technique for a listed contaminant shall *require treatment necessary in the Administrator's judgment to prevent known or anticipated adverse effects on the health of persons to the extent feasible*. (The term *"feasible"* means with the use of the best technology, treatment techniques, and other means, which the Administrator finds are generally available (taking cost into consideration).[14]

Revised national primary drinking water regulations were to be amended "whenever changes in technology, treatment techniques, and other means permit greater protection of the health of persons, but in any event such regulations shall be reviewed at least once every three years."[15]

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[11] H. Report No.93-1185, 1974 USCCAN p. 6472.

[12] Section 1412 (b)(1)(B).

[13] Section 1412 (b)(2).

[14] Section 1412 (b)(3), emphasis added.

[15] Section 1412 (b)(4).

SECONDARY DRINKING WATER REGULATIONS

Unlike the primary regulations, secondary regulations were to be promulgated within twelve months of enactment. The term "secondary drinking water regulation" is defined as a:

> "regulation which applies to public water systems and which specifies the maximum contaminant levels which, in the judgement of the Administrator, are requisite to protect the public welfare. Such regulations may apply to any contaminant in drinking water (A) which may adversely affect the odor or appearance of such water and consequently may cause a substantial number of the persons served by the public water system providing such water to discontinue its use, or (B) which may otherwise adversely affect the public welfare. Such regulations may vary according to geographic and other circumstances.[16]

Secondary regulations "apply to any contaminant in drinking water which (A), may adversely affect the odor or appearance of such water". . . or (B), which may otherwise adversely affect the public welfare.[17] Because they are designed to protect aesthetic rather than health-related characteristics of drinking water, extensive research and data collection were not deemed necessary to develop secondary regulations, and no interim stage was required. A second distinction between the primary and secondary regulations is that primary regulations are enforceable by either EPA or the State (where a State has taken primary enforcement responsibility); secondary regulations "are not Federally enforceable and are intended as guidelines for the states."[18]

UNDERGROUND INJECTION CONTROL (UIC) REGULATIONS

Section 1412 of the SDWA authorizes EPA to promulgate regulations for State underground injection programs. Such regulations shall contain "minimum requirements for effective programs to prevent underground injection which endangers drinking water." Section 1421 (d)(2) states that: "Underground injection endangers drinking water sources if such injection may result in the presence in . . . . any public water system, of any contaminant, and if the presence of such contaminant may result in such system's not complying with any national primary drinking water regulation or may otherwise adversely affect the health of persons". The minimum regulations are to include mandatory permits for all underground injections; and inspection, monitoring, recordkeeping and reporting requirements. There is not an explicit provision for designating specific chemicals requiring regulation; the regulations were designed to be primarily technology-based. In prescribing regulations to control underground injections, the Act requires the EPA Administrator to,

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[16] Section 1401 (2), emphasis added.

[17] Section 1412(c).

[18] 42 FR 17144 (March 31, 1977), emphasis added.

> . . . . to the extent feasible, avoid promulgation of requirements which would unnecessarily disrupt State underground injection control programs which are in effect and being enforced in a substantial number of states.[19]

A regulation is deemed to have a "disruptive" effect "only if it would be infeasible to comply with both such regulation and the State underground injection control program."[20]

BOTTLED DRINKING WATER STANDARDS

The SDWA also contains a brief provision amending the Federal Food, Drug and Cosmetic Act by adding the following new section to cover bottled drinking water:

> "Sec. 410. Whenever the Administrator of the Environmental Protection Agency prescribes interim or revised national primary drinking water regulations under section 1412 of the Public Health Service Act, the Secretary shall consult with the Administrator and within 180 days after the promulgation of such drinking water regulations either promulgate amendments to regulations under this chapter applicable to bottled drinking water or publish in the Federal Register his reasons for not making such amendments."

CASELAW

The Safe Drinking Water Act was reviewed by the District of Columbia Court of Appeals in 1978.[21] In that case, EPA's interim drinking water regulations were challenged as insufficient on a number of specific points and were upheld, for the most part, as a proper exercise of agency discretion "in an area characterized by scientific and technological uncertainty."

A key issue was the proper scope of the interim standards, and this involved an interpretation of the entire statutory scheme. The court reviewed the statutory language and legislative history of the SDWA. It drew two main conclusions from its review:

> (1) Congress "intended the EPA to undertake rapid and comprehensive measures in coping with the problem of unsafe drinking water. It seems particularly clear from the

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[19] Section 1421 (b)(3)(B)(i).

[20] Section 1421 (b)(3)(ii)

[21] EDF V. Costle, 578 F.2d 337 (D.C.Cir. 1978).

> legislative history that Congress contemplated prompt regulation, whenever feasible, of every contaminant identified as possibly injurious to health."
>
> (2) Congress established a "phased" approach to drinking water regulation so that regulation would remain attuned to the "rapidly expanding knowledge of technology."

The Court felt it would be more constructive to assure that future agency action would effectively promote the goals of the SDWA than to fashion remedies to "correct" earlier agency actions. The Court indicated that the on-going nature of the SDWA requires the agency to "keep pace with scientific and technological developments." It added:

> In light of the clear language of the legislative history, the incomplete state of our knowledge regarding the health effects of certain contaminants and the imperfect nature of the available measurement and treatment techniques cannot serve as justification for delay in controlling contaminants that may be harmful.

Where current knowledge of injurious effects and the costs (and efficacy) of monitoring and treatment procedures are better-developed and stable--as for inorganic water contaminants--the situation is somewhat different. The task is one of line-drawing:

> Agency expertise and judgment must be applied in determining the optimal balance between promotion of the public welfare and avoidance of unnecessary expense. We will not interfere so long as the Agency strikes a balance that reasonably promotes the legislative purpose.

Finally, on reviewing the statutory language of the SDWA and its legislative history, the Court concluded that revised drinking water regulations must "be fully comprehensive in scope." Controls are not to be delayed pending the development of more refined data on health effects and more efficient detection and treatment technology. The SDWA authorizes EPA to regulate contaminants despite potential uncertainty about health effects on proper control levels:

> Primary regulations [i.e., both interim and revised] must specify contaminants which in the judgment of the Administrator may have an adverse effect on the health of persons when found in drinking water. The words used by the Committee were carefully chosen. Because of the essentially preventive purpose of the legislation, the vast number of contaminants which may need to be regulated and the limited amount of knowledge presently available on the health effects of various contaminants in drinking water, the Committee did not intend to require conclusive proof

> that any contaminant will cause adverse health effects as a condition for regulation of a suspect contaminant. Rather, all that is required is that the administrator make a reasoned and plausible judgment that a contaminant may have such an effect.[22]

The reviewing court also pointed out that the EPA Administrator must establish a maximum concentration level for, or at least list, each contaminant which, in his judgment, may have any adverse effect on health. This reading is consistent with other decisions construing the preventive nature of environmental protection legislation.

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[22] H.R. Rep. No. 93-1185, 92d long., 2d Sess. (1974) at p.10 (emphasis in original).

THE SAFE DRINKING WATER ACT -- REGULATORY REVIEW

INTRODUCTION

The Safe Drinking Water Act (SDWA) of 1974 authorized EPA to establish three regulatory programs addressing different aspects of drinking water contamination. As the statutory review has indicated, however, only the primary and secondary regulations give EPA the option of designating particular chemicals to be controlled. For this reason, this review will focus specifically on these regulations and not the regulations for underground injection control.

The NAS report required by Section 1412(e) was released in June of 1977. As required by the Act, the report was to (1) review the problem of contaminants in drinking water and (2) recommend maximum contaminant levels (MCLs) for those pollutants identified. Based on these recommendations, EPA was to issue revised primary drinking water regulations to replace any of the interim regulations which required such revision.

The NAS report fulfilled the scientific research aspect of its charge, but stopped short of recommending specific MCLs.[1] Lacking this expected guidance, EPA decided it would not be appropriate to promulgate revised drinking water regulations, as the SDWA had mandated. The interim primary standards are, therefore, still in effect and most are likely to remain in effect through 1981.[2]

Because the SDWA allows for amendments to the interim regulations, however, EPA has been able to use this authority to promulgate additional interim primary standards for substances not covered in the first round of rulemaking. In the recent regulations controlling total trihalomethanes (TTHMs, a group of organic chemicals found in drinking water), EPA explained its statutory authority in the following manner:

> Although Congress clearly contemplated the comprehensive control of organic chemical contaminants in the revised regulations, the statute nowhere precludes EPA from establishing requirements as amendments to the interim regulations even after the issuance of the report of the

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[1] The NAS panel claimed that because it was a scientific research body and not a regulatory authority, it would be inappropriate for them to recommend MCLs which would be the basis for EPA's regulatory actions. (Personal communication with E. Bellack, Office of Drinking Water, EPA, on November 12, 1980.)

[2] *Ibid*.

> National Academy of Sciences under Section 1412(e). The statute does not require that all regulations subsequent to the NAS report be issued as a Revised Regulation. All that is required is that the applicable statutory criteria be met. Given Congress' early concern with the presence of organic chemicals in drinking water, the availability of control measures to reduce the level of TTHMs, . . . and EPA's finding that THMs "may have an adverse effect on the health of persons," amending the Interim Regulations to include these requirements as a first step toward controlling organic chemical contaminants in drinking water is clearly authorized at this time. [44 FR 68625, November 29, 1979 (emphasis added).]

The major differences between interim and revised primary drinking water standards is that the former are to be based on "technologies, treatment techniques and other means . . . generally available" as of December 3, 1974, while revised regulations are to be based on current "generally available" techniques. Thus, interim regulations cannot take advantage of developments in treatment methods over the last six years and are therefore likely to reflect a lower level of control than would be possible under revised standards.

Both of the wording of the statute and the failure of NAS to recommend MCLs or to list those chemicals for which MCLs should be calculated have resulted in EPA being given a significant amount of discretionary authority in establishing national primary drinking water regulations, as will be discussed more fully below.

This section summarizes the major provisions of the SDWA requiring regulatory action by EPA and is organized into the following sections:

- Specification of Chemicals to be Regulated presents the specific factors which must (or may) enter into EPA's decision of whether or not a chemical should be regulated under SDWA.

- Regulatory Provisions and Status of Regulations. This section describes the regulatory provisions developed by EPA to regulate contaminants in drinking water, and the current status of the drinking water standards authorized by the SDWA.

- Summary. The approaches to regulating chemicals embodied in the various regulations are discussed and compared in this final section.

SPECIFICATION OF CHEMICALS TO BE REGULATED

The specification and regulation of contaminants requiring primary standards were the highest priority activities authorized by the SDWA, because these substances are potential human health hazards. This section will: (1)

describe the statutory provisions specifying contaminants which are to be regulated; (2) discuss the policies which EPA has developed for determining the substances for which it will promulgate primary standards; and (3) review the national interim primary drinking water regulations which have been promulgated to date.

Interim and Revised Primary Drinking Water Standards

The general procedures by which a chemical is specified for regulation is authorized by the SDWA. In the six years since enactment, moreover, EPA has used the discretionary authority provided by the Act to define policies and practices for specifying those substances for which regulations are needed.

The SDWA defines substances which can be regulated as "contaminants in water in public water systems, where the term 'contaminant' refers to any physical, chemical, biological, or radiological substance or matter in water."[3] Primary regulations are to specify contaminants "which, in the judgment of the Administrator may have any adverse effect on the health of persons.[4] Both the specification of the anticipated harm ("any adverse effect") and of causality ("may have") are left open to discretionary interpretation on the part of EPA.

Factors and considerations which EPA is directed to take into account when promulgating final regulations differ between interim and revised primary regulations . The interim regulations are required to "protect health to the extent feasible, . . . (taking costs into consideration) . . . ."[5] The term "feasible" is not defined specifically in this context but is later stated to mean "feasible with the use of the best technology, treatment techniques, and other means, which the Administrator finds are generally available."[6]

Revised primary standards, which EPA may promulgate to reflect new data or other information resulting from the NAS study, are to be "set at a level at which . . . no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety."[7]

Once promulgated, revised primary regulations "shall be amended whenever changes in technology, treatment techniques, and other means permit greater protection of the health of persons.[8] As has been noted above, the key difference between the two is the higher level of control afforded by revised regulations, which may specify technologies developed after December 17, 1974.

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[3] Section 1401(6).

[4] Section 1401(1)(B) (emphasis added).

[5] Section 1412(a)(2).

[6] Section 1412(b)(3).

[7] Section 1412(b)(1)(B) (emphasis added).

Criteria and Factors for Regulations

Because the statute provides so little in the way of required procedures, EPA has established administratively the criteria and factors it will consider when (1) specifying contaminants to be regulated and (2) establishing the actual regulations. The basis for both actions is generally best explained in the preamble or body of the regulations themselves. This section describes the factors on which agency decisions were based.

Three specific factors which have been handled somewhat differently in each of the interim primary regulations promulgated to date should be noted at the outset of this discussion. The first is the manner in which chemical compounds are specified in the individual standards; the second addresses the problem of sensitive segments of the population-at-large; and the third relates to the use of "safety factors" in calculating an MCL for a particular substance.

Chemical Specification. With one exception discussed below, the interim regulations for inorganic chemicals do not specify whether a standard refers to a contaminant only in its elemental form or as it is found in certain or all compounds. Clearly such a distinction is important, though it is never addressed in the Preamble or body of the regulations. The only guidance EPA gives at all on this issue is in the prescribed test and measurement procedures. For each contaminant requiring an MCL, EPA specifies the procedure which must be used by state authorities to test for its presence in drinking water supplies. According to an EPA official, these procedures identify the contaminant in all forms, elemental and compound, in which it may be present.[9] Mercury, however, is defined in the regulations as mercury and "mercurial compounds" specifically, for reasons that are not made clear. Moreover, the interim regulations for radionuclides and organic chemicals are extremely specific in defining the exact compounds to which they refer. EPA appears not to have adopted a uniform approach and format in this instance.

Sensitive Subgroups. The effects of a given chemical are rarely, if ever, uniform across the population; certain groups are likely to be more susceptible or sensitive than others. A major issue in regulating such substances is whether standards should be set at a level which protects the population-at-large or set so as to protect these especially sensitive subgroups.

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[8] Section 1401(2) (emphasis added).

[9] Personal communication with E. Bellack, EPA, on October 2, 1980.

The interim primary drinking water regulations promulgated through January 1, 1981, suggest that EPA has adopted a somewhat consistent approach in this area. Three of the substances for which MCLs have been set -- fluoride, lead, and nitrates -- are especially toxic to children or infants. The MCLs for these substances have been set at a level low enough to ensure that children are adequately protected from their toxic effects.

For other chemicals, however, the Agency's policy has not been as uniform. Cadmium, for example, is ingested from cigarette smoke, with the result that smokers have a significantly ihgher total intake than do non-smokers. The MCL was set, nonetheless, so as to provide a four-to-one safety factor for non-smokers; the supporting documentation does not indicate an intent to ensure protection for the more widely exposed smoking population. Similarly, the decision not to set an MCL for sodium was based on the fact that its effects are felt only by a small segment of the population and, for this reason, the Agency could not justify establishing a national sodium standard. Thus, while it is evident that EPA is aware of the "sensitive subgroup" problem, it is not yet apparent what factors will be used to decide which of these groups merit special protection.

Safety Factors. With respect to the "margin of safety" or safety factor employed in calculating MCLs, the Agency not only does not pursue a uniform approach, it specifically states that it has not:

> The standards were not developed by a systematic approach to safety factors, at leat partly because of (1) amount of knowledge about, and (2) the nature of the health risk of, the various contaminants covered a very broad range. The regulations are the result of experience, evaluation of the available data, and professional review.[10]

The final sentence provides a succinct and extremely accurate statement of EPA's overall approach to establishing the interim policy drinking water regulations, as the discussion below seeks to demonstrate.

REGULATORY PROVISIONS AND STATUS OF REGULATIONS

The national interim primary regulations constitute the major portion and the most important of the drinking water regulations (see 40 CFR 141). As of January 1, 1981, regulations have been promulgated for inorganic chemicals and certain pesticides and herbicides, radionuclides, and a specific group of organic chemicals.[11] Exhibit 3-1 shows the chronology of these

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[10] 40 FR 59575 (December 24, 1975). Emphasis added.

[11] National interim primary drinking water regulations for inorganic chemicals and specific pesticides were promulgated at 40 FR 59566 (December 24, 1975); for radionuclides at 41 FR 28402 (July 9, 1976) and for a specific group or organic chemicals (total trihalomethanes) at 44 FR 68624 (November 29, 1979). See 40 CFR 141, Subpart B.

EXHIBIT 3-1

CHRONOLOGY OF SDWA ACTIONS AND REGULATIONS

December 3, 1974	Safe Drinking Water Act (SDWA, PL 93-523) enacted by Congress as an addition to the Public Health Service Act.
March 14, 1974	EPA proposed National Interim Primary Drinking Water Regulations (NIPDWRs) (40 FR 11990).
August 14, 1975	EPA proposed NIPDWRs for Radioactivity (40 FR 34324).
December 24, 1975	EPA promulgated Final NIPDWRs (40 FR 59566).
July 9, 1976	EPA promulgated Final NIPDWRs for Radioactivity (41 FR 28402).
July 14, 1976	EPA issued ANPRM to require control of organic chemicals in drinking water (41 FR 28991).
August 31, 1976	EPA proposed regulations to govern State underground injection control (UIC) programs (41 FR 36730).
March 31, 1977	EPA proposed national secondary drinking water regulations (NSDWRs) (42 FR 17143).
February 9, 1978	EPA proposed amendments to the NIPDWRs to control organic chemical contaminants (43 FR 5756).
April 20, 1979	EPA reproposed UIC regulations (44 FR 23738).
July 19, 1979	EPA promulgated NSDWRs and proposed amendments to NIPDWRs (44 FR 42198, 44 FR 42247).
November 29, 1979	EPA promulgated Final NIPDWRs to control Trihalomethanes (THMs) (44 FR 68624). States must begin monitoring THMs in drinking water by November 29, 1980.
June 24, 1980	EPA promulgated Final Criteria and Standards for the UIC Program (45 FR 42500).
August 27, 1980	EPA amends interim primary drinking water regulations (45 FR 57332).

regulations. While all are part of the same general regulatory package, each regulation was proposed and promulgated separately and reflect somewhat different criteria and approaches, as the discussion below seeks to demonstrate.

Inorganic Chemicals and Organic Pesticides and Herbicides

As Congress had intended when the SDWA was drafted, the interim regulations were based largely on the Public Health Service Drinking Water Standards of 1962. The 1962 standards, which were simply guidelines for state authorities and did not have the force of law, set maximum limits for nine substances.[12] In establishing these limits, the Public Health Service stated that "Drinking water shall not contain impurities in concentrations which may be hazardous to the health of the consumers;" health hazards are defined as "any conditions, devices, or practices in the water supply system and its operation which create, or may create, a danger to the health and well-being of the water consumer." The substances selected for regulation were chosen because (1) they were known to have toxic or deleterious health effects in high doses, (2) scientific methods existed for detecting and measuring their presence in water supplies, and (3) they were known to be frequently occurring in U.S. water supplies.[13]

The 1962 standards were reviewed by EPA in light of data and treatment techniques developed between 1962 and 1974. Of the nine substances for which limits were set in 1962, eight were retained in the final interim primary drinking water standards published in 1975, and two additional substances were added, as presented in Exhibit 3-2. Appendix A to the Regulations, the "Statement of Basis and Purpose," defines the reasoning followed by EPA in reviewing the 1962 Standards and setting appropriate MCLs. The general principles and factors identified include:[14]

(1) The substances represent hazards to the health of man.

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[12] The 1962 Standards (42 CFR Subpart 72) were simply guidelines to public water authorities, with no state or federal force of law. EPA's belief that Congress' intent was that these Standards should serve as the basis for the Interim Regulations is stated at 40 FR 59567, in the Preamble to the NIPDWR final rule.

[13] Personal communication with EPA Office of Drinking Water staff, October 7, 1980.

[14] "National Interim Primary Drinking Water Regulations," EPA 570/9-76-003, pp. 47-128. This EPA publication contains the final regulations as published in the Federal Register, as well as the background information contained in the "Statement of Basis and Purpose" which was released when the regulations were proposed but not published in the Federal Register. For this reason, citations for the Statement of Basis and Purpose (Appendix A of EPA 570/9-76-003) refer to page numbers in that publication.

EXHIBIT 3-2

MAXIMUM CONTAMINANT LEVELS FOR INORGANIC CHEMICALS

Contaminant	MCL, Milligrams Per Liter
Arsenic	0.050
Barium	1.000
Cadmium	0.010
Chromium	0.050
Lead	0.050
Mercury	0.002
Nitrate (as N)	10.000 a/
Selenium	0.010
Silver	0.050
Fluoride	1.4-2.4

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a/ Some non-community systems may exceed the 10 mg/1 MCL up to 20 mg/1 under certain controlled situations.

Source: 42 CFR 141.11(b)

(2) *Total environmental exposure* to a particular contaminant was considered in calculating specific MCLs. In other words, epa attempted to estimate the amount of the substance to which the average peson is likely to be exposed from all sources (air, diet, water, etc.) and then determine the fraction of total intake resulting from ingestion of drinking water.

(3) An attempt was made to *set lifetime exposure limits at the lowest practical level* so as to minimize the amount of the contaminant contributed by drinking water, particularly when other sources are known to represent the major exposure. By "practical" the Agency appears to be referring to two factors: a level that is technologically feasible (taking costs into consideration, as required by the Act) and one that takes account of the fact that drinking water may be only a minor source of the contaminant in the average person's total intake.

(4) The regulations are considered a *standard of quality generally attainable* by good water quality control practices. The policy was to set limits not so low as to be impracticable nor so high as to encourage pollution of water.

(5) *No attempt was made to set MCLs for every toxic or undesirable contaminant* that might enter a public water supply; the regulations set forth in the 1962 Public Health Service Standards formed the basis for EPA's interim primary regulations.

(6) The MCLs were based on an *assumed consumption level of two liters of water per day*.

(7) The MCLs were *not intended to provide a uniform safety factor*, primarily because both the level of knowledge and nature of the health risks of the various contaminants vary widely.

In addition to these general considerations, specific factors were cited for each of the following specified chemicals:

Arsenic is both highly toxic and frequently found in drinking water supplies, as well as in the air and soil. The health effects of both acute and chronic exposure are well documented in laboratory animals and, to a somewhat lesser degree, in humans. Minimum-effect and no-effect levels have been demonstrated in dogs, rats, and mice. There has been some suggestion that arsenic may be carcinogenic, though such evidence is inconclusive.[18]

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[18] EPA 570/9-76-003, pp. 52-53.

EPA review of data generated since the 1962 standard did not indicate that the MCL required revision:

> It is estimated that the total intake of arsenic from food is an average of 900 ug/day. At a concentration of 0.5 mg/liter and an average intake of 2 liters per day, the intake from water would not exceed 100 ug per day, or approximately 10 percent of the total ingested arsenic.... In light of our present knowledge concerning the potential health hazard from the ingestion of arsenic, the concentration...in drinking water shall not exceed .05 mg/1.[16]

Barium is "recognized as a general muscle stimulant, including especially the heart muscle," and "evidence exists for high acute toxicity of ingested barium . . . and for chronic irreversible changes in tissues resulting from the . . . deposition of insoluble forms of barium in sufficient amounts." An MCL was determined to be necessary because of the "seriousness of the toxic effects of barium on the heart, blood vessels, and nerves."[17]

No study has identified the amount of barium that may be tolerated in drinking water. A threshold limit of 0.5 mg/m^3 air set by the American Conference of Governmental Industrial Hygienists in 1958 provided EPA with a "rational basis for a water guideline."[18] On the basis of this limit and by assuming certain rates of absorption into the bloodstream and gastrointestinal tract, a value of 2 mg/l was derived as an approximate maximum concentration level for a healthy adult population. A "safety factor" of two to one, to account for more sensitive segments of the population, was used to derive the MCL of 1 mg/l as constituting a "no-effect" level in water.

The Statement of Basis and Purpose does not discuss the amount of barium typically found in drinking water nor other factors which would indicate why this substance is particularly a problem in drinking water supplies.

Cadium is described as a "nonessential, non-beneficial element of high toxic potential;"[19] evidence of its acute and chronic toxicity is documented by numerous studies. Cadmium is known to enter drinking water supplies as run-off from certain industrial point sources. The average amount of cadmium in U.S. drinking water supplies has been estimated at 1.3 ug/l.

Diet and cigarette smoking -- not drinking water -- are the major sources of ingested cadmium. A review of existing data suggested that 75 ug is a reasonable estimate of average daily dietary intake. The level of exposure which may cause chronic cadmium poisoning is currently unknown, though the studies to date indicate the level to be in the 500-600 ug/day range. The MCL was set at 0.01 mg/l; at the average human consumption of two liters of water per day, it would account for 20 ug/day. Added to the assumed dietary intake of 75 ug/day, the MCL provides a "four-fold safety factor" for nonsmokers.[20] The use of a four-to-one safety factor for cadmium versus the two-to-one safety factor for barium is never discussed or explained.

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[16] *Ibid*., p. 54.

[17] *Ibid*., p. 58.

[18] EPA 570/9-76-003, p. 58.

[19] *Ibid*., p. 59.

Chromium is known to be toxic to humans; to produce lung tumors when inhaled; and to be found in certain foods; air, including cigarette smoke; and some drinking water supplies. Little data are available on either the amount of chromium present in food or the level of daily intake which can be tolerated in humans without adverse health effects. EPA based the MCL of 0.5 mg/l on several recent studies of toxicity from which "it would appear that a concentration of 0.5 mg/l of chromium incorporates a reasonable factor of safety to avoid any hazard to human health.[21] In this case, the margin of safety (i.e., "four-fold" or "two-to-one" as stated for other chemicals) is nowhere given explicitly; "reasonable" is as closely as it is defined in the Statement of Basis and Purpose.

Fluoride is an essential nutrient though it can have adverse and even fatal effects at very high doses. The only harmful effect from excessive fluoride in drinking water observed in the U.S. has been dental fluorosis, particularly among children. Optimum fluoride levels in drinking water are seen as dependent on climatic conditions because the amount of water (and hence fluoride) ingested by children is influenced primarily by temperature. The MCLs set by EPA thus vary with the average temperature of a community, as shown in Exhibit 3-3. The optimum concentration level for a given temperature zone were based on data collected in a 1969 study by the National Institutes of Health (NIH). To arrive at the MCLs, EPA appears to simply have doubled the optimum level and defined this as the MCL for a particular zone. The justification for doubling the optimum level to arrive at the MCLs is not documented in the discussion of this standard, and the standard was challenged in court as a result (Environmental Defense Fund v. Costle, 578 F.2d 337 (D.C. Cir. 1978). The Appeals Court found that EPA had acted within its discretionary authority in setting MCLs for fluoride at twice the optimal level.

Lead is well known to be toxic in both acute and chronic exposures, particularly to young children. A 1969 study estimated that lead concentrations in treated drinking water ranged as high as .64 mg/l, an amount considered potentially excessive, especially to children. To 0.5 mg/l standard was determined to be (1) generally obtainable by most drinking water

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[20] Ibid., p. 61 (emphasis added).

[21] Ibid., p. 63 (emphasis added).

EXHIBIT 3-3

MAXIMUM CONTAMINANT LEVELS FOR FLUORIDE

Temperature Degrees Fahrenheit	MCL, Milligrams Per Liter
53.7 and below	2.4
53.8 to 58.3	2.2
58.4 to 63.8	2.0
63.9 to 70.6	1.8
70.7 to 79.2	1.6
79.3 to 90.5	1.4

Source: 40 CFR 141.11(c)

supplies, and (2) sufficiently low to insure that *total dietary intake of lead by the most vulnerable segment of the population* (children) would be *below the maximum safe level*.[22]

Mercury was not included in the 1962 Standards but was added to the NIPDWRs because (1) it posed *"an unwarranted threat the health,"* and (2) data indicated that mercurial compounds may be present in drinking water supplies.[23] While mercury poisoning may result from acute exposure, the major concern was to guard against the chronic effects resulting from exposure to small amounts over a long period of time.

"Safe levels" were estimated using both laboratory and epidemiological test data. The contribution of other sources of mercury to daily ingestion levels was also considered because "if the total daily intake from all sources (air, water, and food) is approaching 30 mg/person/day, the concentration of mercury . . . will have to be reduced if *a safety factor of 10 is to be maintained*. The MCL of .002 mg/l is seldom exceeded in drinking water, thus "the margin of safety gained from the restricted intake . . . in drinking water can be applied to the total intake with *minimal economic impact*.[24] In other words, because mercury contamination in drinking water can be controlled to very low levels without incurring significant costs, the added margin of safety thereby achieved can help to offset the intake from other sources which may not be as easily controlled.

The mercury standard is interesting because it is one of the few cases where a marginal cost approach to total environmental exposure has been applied to health and safety regulation. It is the only such standard promulgated under the SDWA, though an explanation of why this approach was taken, and why only for mercury, is not provided in the supporting documentation.

This standard is also unusual because it is the only one which specifically states that both mercury and "mercurial compounds" are to be regulated. All of the other standards simply rely on the prescribed test procedures to indicate that the MCL refers to compounds as well as elemental forms of the substance.

Nitrate at levels greater than 10 mg/l in drinking water has been serious or fatal to infants, although U.S. water supplis have frequently exceeded this level with only one such case of nitrate poisoning reported. The poisoning process is poorly understood; additional study was stated to be necessary to determine more precisely the level at whch adverse health effects can be prevented completely.

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[22] *Ibid*., p. 71-72 (emphasis added).

[23] *Ibid*., p. 76 (emphasis added).

[24] *Ibid*., p. 79 (emphasis added).

The MCL of 10 mg/1 was selected because "for *the usual situation* (it) will *protect the majority of infants*." While MCLs are legally enforceable, the discussion of nitrate in the Statement of Basis and Purpose states that: "If a water supply cannot maintain the NO_3-N concentration below the limit, *diligent efforts must be made to assure that the water is not used for infant feeding*."[25] The rules have been amended to allow some non-community systems to exceed the 10 mg/1 MCL up to 20 mg/1 under certain controlled situations.[26]

Selenium was included in the 1962 Standards because of its possible carcinogenicity; recent studies have not supported this potential health effect, however. Other apparent health effects include loss of hair, decreased mental alertness, and gastrointestinal problems, though the levels of selenium intake resulting in these effects is disputed.[27] Based on a review of the existing data, the MCL of 0.01 mg/1 set by EPA "results in a minimum safety *factor of 3*, considering the lower end of the range of selenium intakes that have been associated with minor toxic effects. . . ."[28]

Silver is intentionally added to some drinking water supplies as a disinfectant. Its chief effect on humans is cosmetic: permanent discoloration of the skin, eyes, and mucous membranes. Silver at very high concentrations has caused diseases of the kidneys, liver and spleen in laboratory rats. Some evidence indicates that, once absorbed, silver is held indefinitely in tissues. A review of data generated since the 1962 levels were set apparently did not suggest a need to revise the 1962 Standard of 0.05 mg/1.

Sodium was not included in the 1962 Standards, but public comment on the proposed Interim Primary Regulations suggested an MCL was necessary. EPA reviewed existing data on possible health effects and average sodium concentration in U.S. drinking water and concluded:

> . . . the available data do not support any particular level of sodium in drinking water, and the regulations of sodium by a maximum containment level is a *relatively inflexible, very expensive means* of dealing with a problem which varies greatly from person to person.[29]

The basis for the decision not to set an MCL was the fact that sodium is only a "hazard" for the small fraction of the population which is especially

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[25] *Ibid*., p. 82 (emphasis added).

[26] See 43 FR 37332, 40 CFR 141.11(b).

[27] *Ibid*, pp. 114-5.

[28] *Ibid*., p. 116.

[29] *Ibid*., p. 122 (emphasis added).

sensitive to it and must follow a special low-sodium diet. Setting a federally-enforceable standard to protect a small segment of the population, therefore, did not seem an appropriate or justifiable course of action. Instead, EPA recommended communities with high levels of sodium in drinking water supplies to notify consumers of this fact, so that members of the community with special sensitivities could make other arrangements to acquire water for drinking.

Organic pesticides and herbicides were not included in the 1962 Standards but, as EPA stated in the Preamble to this proposed regulation, data collected in the intervening period indicated that: (1) acute and chronic health effects on the muscle and nervous systems appear to result from exposure to certain pesticides; (2) several widely-used pesticides may be possible carcinogens; (3) no well-documented safe or minimal effect levels had yet been determined; and (4) considerable additional study was needed before the effects of these substances in the general environment, and specifically in drinking water, would be known. (40 FR 11991)

At the time the Interim Primary Regulations were proposed, EPA had recently cancelled all use of DDT and suspended the major uses of Aldrin/Dieldrin, exercising its authority under FIFRA.[30] MCLs for these substances were not proposed, therefore, until ongoing research could determined the extent to which these chemicals might continue to persist in drinking water. Similarly, the proposed MCLs for chlordane, heptachlor, and heptachlor epoxide were deleted from the Final Interim Regulations because EPA was involved at the time in suspension and cancellation hearings for these pesticides.[31]

The "approval limits" or MCLs for the six chemicals are presented in Exhibit 3-4 and were derived from: (1) available studies on acute and long-term effects on animals, (2) a factor to adjust these data to a relevant human body tolerance, (3) consideration of total environmental exposure to the substance, and (4) inclusion of a "conventional safety factor" to extrapolate animal exposure to appropriate human levels. The derivation methodology is shown in Exhibit 3-5.

Radioactivity

Although radioactivity was not regulated in the 1962 Standards, EPA nonetheless determined it was necessary to establish MCLs for certain natural and human-made radioactive substances which unavoidably enter water supplies. Interim primary drinking water regulations for radioactivity were proposed on August 14, 1975 and promulgated on July 9, 1976.[33]

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[30] A discussion of this situation is given in the preamble to the proposed interim drinking water regulations, 40 FR 11991 (March 14, 1975).

[31] 40 FR 59578.

[32] EPA 570/9-76-003, pp. 104 and 110 (emphasis added).

[33] 40 FR 34324 and 41 FR 28402 respectively.

EXHIBIT 3-4

MAXIMUM CONTAMINANT LEVELS FOR ORGANIC PESTICIDES AND HERBICIDES a/

	MCL, Miligrams Per Liter
(a) Chlorinated hydrocarbons:	
Endrin (1,2,3,4,10, 10-hexachloro-6,7-epoxy-1,4, 4a, 5,6,7,8, 8a-octahydro-1,4-endo, endo-5, 8-dimethano naphthalene).	0.002
Lindane (1,2,3,4,5, 6-hexachlorocyclohexane, gamma isomer).	0.004
Methoxychlor (1,1,1-Trichloro-2,2-bis [p-methoxyphenyl]	0.1
Toxaphene ($C_{10}H_{10}Cl_8$-Technical chlorinated camphene, 67-69 percent chlorine)	0.005
(b) Chlorophenoxys:	
2,4-D, (2,4-Dichlorophenoxyacetic acid.)	0.1
2,4,5-TP Silvex (2,4,5-Trichlorophenoxypropionic acid)	0.1

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a/ The Maximum Contaminant Level (MCLs) apply only to community water systems. Community water systems are defined as those which serve "at least 15 service connections used by year-round residents or . . . at least 25 year-round residents." 40 CFR 141.2(e)(i).

EXHIBIT 3-5

Derivation of Approval Limits (ALs) for Chlorinated Hydrocarbon Insecticides

	Lowest Long-Term Levels With Minimal or No Effects			Calculated Maximum Safe Levels			Intake from Diet		Water	
Compound	Species	ppm in diet	mg/kg/body weight/day a/	Safety Factor (X)	mg/kg/day	mg/man/day b/	mg/man/day	Percent of (d) Safe Levels	Percent of Safe Level	Recommended MAL (mg/l) c/
Endrin	Rat	5.0(3)	0.83	1/500	0.00166	0.1162	0.00035	4.1	20	0.0002
	Dog	1.0(3)	0.02	1/500	0.00004	0.0028d/				
	Man	N/A	N/A	--	--	--				
Lindane	Rat	50.0(2)	8.3	1/500	0.00166	1.162				
	Dog	15.0(2)	0.3	1/500	0.00006	0.042d/	0.0035	8.3	20	0.004
	Man	N/A	N/A	--	--	--				
Methoxychlor	Rat	100.0(2)	17.0	1/100	0.17	11.9				
	Dog	4000.0(2)	80.0	1/100	0.3	21.0	T	T	20	0.1
	Man	--	2.0(5)	1/100	0.02	1.4d/				
Toxaphene	Rat	10.0(2)	1.7	1/500	0.0034	0.238d/	T	T	20	(0.025)f/ 0.005e/
	Dog	400.0(2)	8.0	1/500	0.016	1.12				
	Man	N/A	N/A	--	--	--				

a/Assume weight of rat = 0.3 kg and of dog = 10 kg; assume average daily food consumption of rat = 0.5 kg and of dog = 0.2 kg.
b/Assume average weight of human adult = 70 kg.
c/Assume average daily intake of water for man = 2 liters.
d/Chosen as basis on which to derive MAL.
e/Adjusted for organoleptic effects.
f/Calculated MAL in parentheses.
N/A--no data available.
T--Infrequent occurrence in trace quantities.

		Lowest Long-Term Levels with Minimal or No Effects	Calculated Maximum Safe Levels from all Sources of Exposure			Water	
Compound	Species	mg/kg/day a/	Safety Factor (X)	mg/kg/day	mg/man/day b/	Percent of Safe Level	AL (mg/l) c/
2,4-D	Rat	50 (6)	1/500	0.1	7.0		
	Dog	8.0 (6)	1/500	0.016	1.12d/	20	0.1
2,4,5-TP	Rat	2.6 (12)	1/500	0.005	0.35		
	Dog	0.9 (12)	1/500	0.002	0.14d/	20	0.01

a/Assume weight of rat = 0.3 kg and of dog = 10 kg assume average daily food consumption of rat = 0.05 kg and of dog = 0.2 kg.
b/Assume average weight of human adult = 70 kg.
c/Assume average daily intake of water for man = 2 liters.
d/Chosen as basis on which to derive AL.

Source: EPA 570/9-76-003, pp. 105 and 111.

In the Preamble to the proposed regulation, the Agency indicated that although radioactive substances in drinking water supplies were not now a serious problem, the regulations were necessary, in part, to ensure that the situation did not become serious:

> EPA recognizes that the normal use of radionuclides in medicine and industry and the utilization of nuclear power to supply some energy needs will unavoidably lead to some radioactivity entering the aquatic environment so that the quality of some surface waters is likely to decrease slightly in the future. (40 FR 34324)

Although this increase in radioactivity in drinking water generally would be small, the Agency believed the risk of future contamination warranted "vigilence." Specific MCLs were set for four radioactive substances or combinations of substances, as listed in Exhibit 3-6. These substances were selected for regulation because they were most likely to be present in public water systems.

Several factors were considered in setting the MCLs for radioactive substances, including the following assumpions and principles:[34]

(1) EPA assumed that no harmless dose of ionizing radiation exists; adverse health effects are assumed to be linearly relatd to dose, with no threshold level.

(2) The low doses and dose rates expected from the intake of drinking water pose only a small potential increase over the normal incidence of certain diseases.

(3) The extent of harm resulting from such low doses can be extrapolated from the effects observed at higher doses and dose rates.

(4) In general, MCLs were selected so as to provide uniform protection of individuals at reasonable cost.

(5) Where the cost of reducing the potential health risk could be calculated, a level of control was selected which balanced "reduction in health risks with the cost of attaining the desired standard."[35]

The last two factors warrant additional discussion, because is it through such issues as "uniform protection," "reasonable cost" and "risk-cost balancing" that EPA addresses the question of risk/benefit trade-offs.

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[34] EPA 570/9-76-003, pp. 129-30.

[35] 40 FR 34324.

EXHIBIT 3-6

MAXIMUM CONTAMINANT LEVELS FOR RADIOACTIVE SUBSTANCES

Naturally Occurring:

Combined radium-226 and radium-228	5 pCi/liter
Gross alpha particle activity (including radium-226 but excluding radon and uranium)	15 pCi/liter

Produced by Human Activity:

(a) The average annual concentration of beta particle and photon radioactivity from man-made radionuclides in drinking water shall not produce an annual dose equivalent to the total body or any internal organ greater than 4 millirem (mrem)/year.

(b) Except for the radionuclides listed in Table A, the concentration of man-made radionuclides causing 4 mrem total body or organ dose equivalents shall be calculated on the basis of a 2 liter per day drinking water intake using the 168 hour data listed in "Maximum Permissible Body Burdens and Maximum Permissible Concentration of Radionuclides in Air or Water for Occupational Exposure, NBS Handbook 69 as amended August 1963, U.S. Department of Commerce. If two or more radionuclides are present, the sum of their annual dose equivalent to the total body or to any organ shall not exceed 4 millirem/year.

Table A.--Average annual concentrations assumed to produce a total body or organ dose of 4 mrem/year.

Radionuclide	Critical Organ	pCi per liter
Tritium	Total body	20,000
Strontium	Bone marrow	8

Source: 42 CFR 141.15-16.

In developing the regulations, EPA considered two possible approaches: uniform MCLs based on the cost-effectiveness of various levels of risk reduction, and variable requirements based on the aggregate dose received by the total population utilizing a given public water system.

Under the first system, EPA would estimate the reduction in health risks associated with different levels of control, balancing these benefits against the costs of achieving them, and selecting a single MCL which provided the best balanceof these two factors. With the second approach, EPA would establish differential MCLs, requiring stricter controlsfor water systems seving larger populations. Such regulations are likely to be more cost-efficient because (1) the costs of control can be spread over a large number of consumers, and (2) greater protection is provided where its effects will be felt by the most people.

The Agency chose the first alternative as the basis for the regulations on "equity considerations" because an aggregate level would have provided for "varying degrees of health protection." [40 FR 34325] "Reasonable cost" was evaluated on the basis of the estimates provided in Exhibit 3-7. An MCL of 0.5 pCi/1, which would provide the greatest degree of risk reduction, was rejected because the annual cost was "considered incommensurate with the potential risk;" similar arguments were made against the other extremely strict limits. Thus, the Preamble suggests that "reasonable" is a flexible concept, one which is based on a discretionary notion of "balancing" rather than a strictly-calculated formula or rule.

Risk estimates were made using data presented in a 1972 report published by the NAS Advisory Committee on the Biological Effects of Ionizing Radiation.[36] Estimates were for the U.S. population in 1967 and indicated, for example, that the individual risk of a fatal cancer from a lifetime total body dose of 4 mrem per year (the MCL for human-made radionuclides) ranged between .4 to 2 x 10^{-6} per year, dpending on whether an absolute or relative risk model was used. Absolute risk estimates were based on the reported number of cancer deaths per rad; relative risk estimates on the percentage increase in cancer mortality per rad. The NAS Committee did not favor one model over the other; their "most likely estimates" represent an average of the two estimates. EPA used these data and risk estimates as guidance to derive the estimated total number of lives saved per year for various control limits, as presented in Exhibit 3-7.

Naturally-occurring radioactivity. Based on a sample of water systems which had been monitored for radium concentration and the assumption of a linear relationship between dose and effect, EPA developed the iformation presented in Exhibit 3-7 to compare the dollar cost and health savings of various levels of control. The MCL of 5 picocuries per liter (pCi/leter) for

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[36] "The Effects on Populations of Exposure to Low Levels of Ionizing Radiation," NAS, National Research Council (NRC): November 1972.

EXHIBIT 3-7

COMPARISON OF RADIUM CONTROL LIMITS

Control Limit pCi Per Liter	Estimated Number of Supplies Impacted	Annual Cost to Achieve Limit	Estimated Total Number of Lives Saved Per Year
9	240	$ 1,400,000	.6
8	300	2,400,000	1.1
7	370	3,400,000	1.6
6	450	5,600,000	2.5
*5	500	8,800,000	3.7
4	670	14,000,000	5.5
3	800	24,000,000	8.2
2	860	36,000,000	11
1	980	70,000,000	15
0.5	1,100	$100,000,000	20

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*Level at which regulation was set.

radium was selected because EPA believed that "because of the limited data on the cost of radium removal and the extent of radium contamination in community water supplies currently available, it would be unwise to prescribe radium removal at concentrations lower than 5 pCi/liter."[37]

In addition, an MCL was set for gross alpha particle activity, defined as "total radioactivity due to alpha particle emission as inferred from measurements on a dry sample."[38] EPA justified placing a limit on gross alpha particle activity rather than each alpha particle-emitting radionuclide individually because it was impractical, at the time the regulations were promulgated, to require identification of all such radionuclides because of the analytical costs which would be incurred. [p. 134]

Human-made Radionuclides. The major sources of radioactivity created by human activities are nuclear power plants, medical sources and nuclear weapons testing.[39] The MCL for radioactivity from human activities, 4 millirems per yars, was calculated based on the asumed intake of two liters of water per day. The 4 millirem standard "was chosen on the basis of avoiding undesirable future contamination of public water supplies as a result of controllable human activities . . . [it] is not anticipated that the maximum contaminant level for man-made radioactivity will be exceeded except in extraordinary circumstances."[40]

In setting this MCL, EPA pointed out that although "man-made radioactivity in public water systems is sometimes a manner of concern, it is important to recognize that . . . current ambient concentrations are less than the proposed limits because of regulatory concern for these radionuclides . . . [and because] . . . drinking water is not a major pathway for exposure . . . .[41]

In addition to human-made radioactivity in drinking water from effluents discharged by nuclear facilities, surface waters may contain radioactive substances resulting from airborne releases of effluents and from nuclear weapons testing. Of primary concern from these sources are strontium-90 and tritium and for this reason, EPA adopted specific MCLs for these two sources of radioactivity. Although data on the effects of these substances on water supplies were incomplete, available data indicated that strontium-90 concentrations averaged about 1 pCi per liter (corresponding to a total body dose equivalent of less than 0.2 mrem per year).[42] The discussion indicate how these ambient concentrations were used to derive the MCLs presented in Exhibit 3-6.

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[37] EPA 570/9-76-003, p. 136. Much of the discussion in this section derives from this report, especially pp. 129-141.

[38] 40 CFR Part 141.2(m).

[39] Ibid., p. 130.

[40] 40 FR 34327.

[41] EPA 570/9-76-003, p. 137.

[42] Ibid., p. 130.

Organic Chemicals

When the Interim Regulations for inorganics and certain organic pesticides and herbicides were proposed, EPA deliberately deferred promulgating standards for other organic chemicals, and instead required public water systems to begin regular monitoring for a number of organic pollutant parameters for which the Agency was contemplating setting standards, including carbon chloroform extract (CCE), volatile and non-volatile total organic carbon (VTOC and NVTOC), total organic chlorine (TOCl), ultraviolet absorbancy, and fluorescence. The reason for taking this course of action was to gather additional data on the extent to which organics in drinking water are a problem. In July of 1976, EPA issued an Advance Notice of Proposed Rulemaking (ANPRM)[43] listing several factors about organics and the need for regulation:

(1) Organics (synthetic and natural) are present in all sources of drinking water to some extent. Synthetic organics are created by the addition of chlorine (used as a disinfectant) to drinking water.

(2) Most organic compounds in drinking water have not been specifically identified and analysis for many is very difficult.

(3) Of the identified organics in drinking water, few have been bioassayed.

(4) Some of the compounds that have been identified are "toxicants, mutagens, and teratogens" as indicated by animal bioassays conducted at high doses.

(5) The effects of long-term, low level exposure on humans is not known.

(6) Some preliminary studies have suggested but not concluded that there is a correlation between cancer mortality and the concentration of certain organics in drinking water.

(7) With the passage of the SDWA, Congress intended that "at least some organics in drinking water would be regulated." This intent is made clear in the Legislative History which states that:

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[43] 41 FR 28991.

> . . . the [Interstate and Foreign Commerce] Committee anticipates that revised national primary drinking water regulations would include regulation of organics as a group and subgroups, such as haloethers, polycyclic aromatic hydrocarbons, and nitrosamines [Legislative History, p. 6464].
>
> In addition, Section 1442(a)(10) of the SDWA which directs EPA to carry out a study of the "reaction of chlorine and humic acids (organic substances) and the effects of the contaminants which result from such reaction on public health and on the safety of drinking water, including any carcinogenic effect."

(8) Treatment for the control of organics is not widely practiced in the U.S. and would impose an added expense on public water systems.

Given these facts, EPA concluded, a course of action was not clear, although some action was necessary. A probable factor in the decision to regulate organics at that time was a suit filled by the Environmental Defense Fund (EDF), pending in the U.S. Court of Appeals, which challenged EPA for not including regulations for organics in the 1975 Interim Primary Regulations.[44/]

The regulatory options under the SDWA were to establish MCLs for individual compounds, groups of compounds or general contamination indicators, and/or to establish technology-based treatment requirements. EPA articulated the advantages and disadvantages of the three options in the ANPRM to the proposed regulations (at 28995-6). The main arguments against MCLs for specific chemicals were limited availability of health data to support individual limits, the difficulty in isolating and measuring individual organic chemicals in water, and the cost of monitoring for such a potentially large number of substances.

Disadvantages of setting an MCL for a single "general organic contaminant indicator" are that such indicators are less sensitive measures of contaminant content, cannot distinguish which organic chemicals might be present, and cannot be correlated with a direct health effect for purposes of selecting an appropriate MCL.

The major trade-off between the two approaches was the higher cost and current scientific uncertainty of setting MCLs for specific substances versus the relative insensitivity and potentially lower level of health protection of the general indicator strategy. Technology-based standards were seen as a way of ensuring that even those organics which could not yet be identified and monitored would be controlled, although to an as-yet unspecified level.

[44/] *EDF v. Costle*, 578 F.2d 337 (D.C. Cir. 1978).

EPA published lengthy proposed regulations in February 1978 and final regulations were adopted in November of 1979.[45] The Interim Regulations included two requirements: an MCL of 0.10 mg/l for total trihalomethanes (TTHMs) including chloroform,[46] and a treatment technique requiring the use of granular activated carbon (GAC) to filter organic materials out of drinking water supplies. EPA identified a number of factors which influenced the regulations finally adopted:[47]

(1) Conclusive proof of an adverse health effect is not a prerequisite to regulation; available data suggest that THMs may have such an effect and therefore should be regulated.

(2) THMs, especially chloroform, are generally present in greater concentrations than other organic chemicals in drinking water, thus facilitating feasible monitoring and analytical techniques. Moreover, THMs as a group are similar enough to allow a single MCL for total THM concentration.

(3) The health effects data, including bioassay, monitoring, mutagenicity, and epidemiology are further developed for chloroform, and by implication for THMs, than for other organic chemicals in drinking water.

(4) THMs are more ubiquitous contaminants in drinking water than other synthetic organics.

(5) Several treatment procedures are available for controlling THMs in drinking water.

In addition, EPA utilized principles articulated in the NAS report on drinking water[48] in its rationale for these regulations:

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[45] 43 FR 5756 (February 7, 1978) and 44 FR 68624 (November 29, 1979) respectively.

[46] In the final regulations, trihalomethane (THM) is defined as "one of the family or organic compounds, named as derivatives of methane, wherein three of the four hydrogen atoms in methane are each substituted by a halogen atom in the molecular structure." Total trihalomethanes (TTHMs) refers to "the sume of the concentration in milligrams per liter of the trihalomethane compounds (trichloromethane [chloroform], dibromochloromethane, bromodichloromethane, and tribromomethane [bromoform]), rounded to two significant figures."

[47] 43 FR 5763 (February 9, 1978).

[48] NAS, Drinking Water and Health, Vol. 1 (1977).

(6) Effects in animals, properly qualified, are applicable to man.

(7) Methods do not now exist to establish a threshold for long-term effects of toxic agents.

(8) Exposure of experimental animals to toxic agents in high doses is a necessary and valid method of discovering possible carcinogenic hazards in man.

(9) Materials should be assessed in terms of human risk, rather than as "safe" or "unsafe." In its explanation of this principle, the NAS report stated that "The limitations of the current experimental techniques do not allow us to establish safe doses, but with the help of statistical methods, we may be able to estimate an upper limit of the risk to human populations. To calculate such a risk, we need data to estimate population exposure; a valid, accurate, precise and reproducible assay procedure in animals; and appropriate statistical methods.[49]

The actual MCL of 0.10 mg/l was based on a "balancing of public health considerations and feasibility of achievement."[50] The phasing-in approach used in the required treatment protion of the regulations is a further indication of EPA's attempt to balance the benefits of reduced risk to human health against the cost of achieving this reduction.

That EPA has stayed within its legal mandate in developing and promulating drinking water regulations is evidenced by the decision in EDF v. Costle, cited above. In its decision of February 10, 1978, the U.S. Court of Appeals for the District of Columbia "found that EPA could exercise a degree of administrative discretion in deciding whether to control organic chemical contaminants under the NIPDWR."[51] The Court deferred final resolution of the issue, however, by remanding the record to EPA to report on "significant changes that have occurred, since the promulgation of the interim regulations, in [EPA's] assessment of the problem of controlling organic contaminants in drinking water" and to advise the Court "as to whether its plans to propose amended interim regulations in light of newly acquired data."

Thus, although EPA's future discretionary authority remains intact, it is likely to be carefully scrutinized by third party interest groups and, by extension, the Courts.

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[49] NAS, Drinking Water and Health, p. 56.

[50] 43 FR 5764.

[51] 578 F.2d 337.

Secondary Drinking Water Regulations

The purpose of secondary regulations, to "protect the public welfare," is both less immediate and less difficult to fulfill. The SDWA mandated, therefore, that final secondary standards be established quickly, based on available data. While the standards refer to either specific substances or specific drinking water quantities, they are necessary only for aesthetic rather than human health considerations.

Specification of Substances Regulated. Secondary regulations must specify "contaminants in public water systems" but are to cover only those contaminants "which *may adversely affect the odor or appearance of such water* . . . or . . . which may *otherwise affect the public welfare*." The sole reference to possible effects of these contaminants is that they "consequently *may cause a substantial number of the persons served by the public water system . . . to discontinue its use*."

Status of the Regulations. Secondary drinking water regulations to "protect the public welfare" were promulgated on July 19, 1979.[52] The regulations identified several known contaminants of drinking water supplies and established non-enforceable "guidelines" to assist States in keeping these contaminants at a level which minimizes their undesirable effects. These limits are presented in Exhibit 3-8.

In general, the effects caused by a contaminant which specify it as one requiring secondary regulation are discoloration, bad odor or unpleasant taste, staining of laundry or plumbing, or certain mild but unpleasant health effects. Exhibit 3-9 indicates the qualities of the various contaminants which caused them to require secondary regulation.

SUMMARY

The SDWA delegates considerable discretionary authority to EPA as to which chemicals will be regulated and the type of regulations that will be imposed. The standards promulgated to date indicate that EPA has indeed taken a flexible approach in setting the interim primary drinking water regulations. Moreover, on the basis of these regulations, some general comments can be made about the way in which EPA has exercised its authority under the SDWA.

The Agency has followed a fairly conservative strategy with respect to previously-regulated contaminants. With the few exceptions noted earlier, the guidelines set forth in the 1962 Standards remain unchanged by the 1975 Interim Primary Regulations. To a large extent, the decision not to change the standards represents the fact that data obtained since 1962 has tended to support the concentration limits set at that time.

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[52] 44 FR 42195.

EXHIBIT 3-8

SECONDARY MAXIMUM CONTAMINANT LEVELS

Contaminant	Level
Chloride	250 mg/1
Color	15 color units
Copper	1 mg/1
Corrosivity	Noncorrosive
Foaming Agents	0.5 mg/1
Iron	0.3 mg/1
Manganese	0.05 mg/1
Odor	3 threshold odor number
pH	6.5-8.51
Sulfate	250 mg/1
Total dissolved solids (TDS)	500 mg/1
Zinc	5 mg/1

Source: 40 CFR 143.3

EXHIBIT 3-9

EFFECTS OF CHEMICALS REGULATED BY SECONDARY STANDARDS

	TYPE OF UNDESIRABLE EFFECT			
Chemical	Bad Odor or Taste	Causes Stains	Discolors Water	Other
Chloride	X			
Copper	X			
Corrosivity		X		Dissolves metals
Foaming Agents	X		X	"Unaesthetic"
Hydrogen Sulfide	X	X		
Iron	X	X	X	
Manganese	X			
Sulfate	X			Laxative effect
Total Dissolved Solids (TDS)	X		X	
Zinc	X		X	

It can also be seen, however, as an indication that EPA considers such regulations to be adequate and the pollutants in question not to warrant excessive time and resources spent reviewing them extensively. While this sentiment is nowhere expressed directly, it is apparent that these, the more traditional drinking water contaminants, are not the major concern of either the Agency or the scientific community in general at this time. Major emphasis, for several years to come, is likely to focus on the expansion and revision of the regulations controlling organic chemicals.

The Agency has employed a conscious cost-effectiveness approach to regulating potential carcinogens. From this perspective, the recently-promulgated THM regulations provide the most telling indication of how the Agency is likely to handle low-level, long-term exposure to carcinogens in drinking water. On the one hand, conclusive proof of carcinogenicity is not to be required as a prerequisite for regulation, the "threshold" concept has been repudiated, and high dose, short-term animal studies have been supported as "necessary and valid" test methods. On the other hand, however, the Agency has explicably stated its intention to balance the benefits of reduced risk to human health against the cost of achieving this reduction. The estimates developed to compare various levels of control for radium (Exhibit 3-7) provide a tangible example of this type of balancing effort. The approach has not been (and is not likely to be in the future) wholly consistent across chemicals. (An indication of this inconsistency is the different margins of safety or "safety factors" used in calculating various MCLs.) The differences reflect the significant disparities in data bases, monitoring ability, and level of knowledge which can be brought to bear on the regulatory process. It is unlikely that these disparities will decrease significantly at any point in the near future.

The ability to identify and measure contaminants in drinking water is a critical constraint. Although this fact is never articulated in any formal way, EPA personnel have stated that it is a primary determinant in specifying chemicals for possible regulation under the SDWA. Setting a standard for total trihalomethanes rather than for several specific compounds is a recent indication of how human health considerations may be constrained by as-yet imperfect scientific methods.

The control of organic chemicals is clearly the major effort EPA will be making in the drinking water area over the next several years, for two key reasons. On the one hand, available data indicate that such chemicals are likely to be highly toxic as well as carcinogenic and mutagenic, though data on dose-response levels are still insufficient. On the other, scientific methods for identifying and detecting all of these substances are presently inadequate and will require considerably more research. The Agency itself acknowledges the continued emphasis on organic contaminants in the proposed TTHM regulations:

> . . . an MCL of 0.10 mg/l for TTHM has been proposed . . . as a reasonable level providing health protection to the extent feasible. This should not lead to complacency on the part of [public drinking water] systems with a THM of 0.09 mg/l for example, but should be construed only as a starting point which will, over time, be lowered progressively as technologic, economic and practical contrainsts permit. (43 FR 5763)

MARINE PROTECTION, RESEARCH, AND SANCTUARIES ACT (MPRSA) -- STATUTORY REVIEW

BACKGROUND

This act, commonly known as the Ocean Dumping Act of 1972,[1] was designed to fill regulatory gaps in the protection of the marine environment and public health. Rather than designate specific materials to be regulated, the statute declares all materials dumped in ocean waters to be regulated substances.

Publicity in 1970 over the dumping of herbicide compounds and nerve gas rockets once intended for chemical warfare made Congress aware of the need for more protection of ocean waters. A 1970 CEQ study[2] pointed out the gaps in the regulation of ocean waters, supplied data on the large quantities of material then being dumped, and discussed the hazards of ocean dumping. This study also served as the basis for the congressional development of legislation which gave EPA discretionary authority to regulate ocean dumping.

REGULATORY CRITERIA

Section 102(b) declares it the Congressional policy "to regulate the dumping of all types of materials into ocean waters and to prevent or strictly limit the dumping into ocean waters of any material which would adversely affect human health, welfare, or amenities, or the marine environment, ecological systems, or economic potentialities".[3]

The definition of the word "material" is all-inclusive:

> "Material" means matter of any kind or description, including, but not limited to, dredge material, solid waste, incinerator residue, garbage, sewage, sewage sludge, munitions, radiological, chemical, and biological warfare agents, radioactive materials, chemicals, biological and laboratory waste, wreck or discarded equipment, rock, sand, excavation debris, and industrial, municipal, agricultural, and other waste; but such term

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[1] 33 USC §1401 et seq. The MPRSA preempts state regulations. Save Our Fisheries Assoc. v. Callaway, 7 ERC 1445 (R.I. 1974).

[2] Senate Report 92-451, as cited in 1972 U.S. Code Congressional and Administrative News, p. 4234.

[3] 33USC §1401(b).

does not mean sewage from vessels within the meaning of section 312 of the Federal Water Pollution Control Act, as amended (33 USC 1322)."[4]

Radiological, chemical, and biological warfare agents, and high-level radioactive wastes, are never permitted to be dumped.[5] For other materials, EPA is delegated authority to grant permits to transport for dumping "where the Administrator determines that such dumping will not unreasonably degrade or endanger human health, welfare, or amenities, or the marine environment, ecological systems, or economic potentialities". EPA is authorized to establish "criteria" upon which to evaluate permit applications.

The MPRSA provides that in establishing or revising ocean dumping permit criteria the EPA shall consider at least the following factors[6]:

(A) The need for the proposed dumping.

(B) The effect of such dumping on human health and welfare, including economic, esthetic, and recreational values.

(C) The effect of such dumping on fisheries resources, plankton, fish, shellfish, wildlife, shore lines and beaches.

(D) The effect of such dumping on marine ecosystems, particularly with respect to

(i) the transfer, concentration, and dispersion of such material and its byproducts through biological, physical, and chemical processes;

(ii) potential changes in marine ecosystem diversity, productivity, and stability; and

(iii) species and community population dynamics.

(F) The effect of dumping particular volumes and concentrations of such materials.

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[4] Section 103(c); 33 USC §1401(c). Oil within the meaning of Section 311 of the Federal Water Pollution Control Act, as amended (33 USC §1321), shall be included only to the extent that such oil is taken on board a vessel or aircraft for the purpose of dumping.

[5] High level radioactive wastes are defined in USC §1402(j).

[6] Section 102a.

(E) The persistence and permanence of the effects of the dumping.

(G) Appropriate locations and methods of disposal or recycling, including land-based alternatives and the probable impact of requiring use of such alternate locations or methods upon considerations affecting the public interest.

(H) The effect on alternate uses of oceans, such as scientific study, fishing, and other living resource exploitation, and nonliving resource exploitation.

(I) In designating recommended sites, the Administrator shall utilize wherever feasible locations beyond the edge of the Continental Shelf.

These factors need not result in criteria which must be applied in every case. Rather, the EPA can weigh and consider these factors and need not include them all in its criteria. This was established by the case discussed next.

A recent Appeals Court case reviewed a challenge to EPA's authority to establish different and less stringent criteria for dumping dredged wastes than for non-dredged materials. The Court held that the MPRSA gives "unqualifiedly broad authority to the [EPA] Administrator to weigh and consider the evaluation factors" in developing criteria for permits. The EPA has the authority "to conclude that certain statutory evaluation factors are inapplicable to a class or type of material". Based on the statutory language and a review of the legislative history, the Court found that EPA had sufficient discretion to determine that, in certain respects, dredged wastes differ significantly from nondredged wastes.[7] However, the Court remanded the regulations to EPA for further action because the government had failed to adequately explain its rationale for disparate treatment of the two categories of wastes.

The agency has much discretion in issuing permits so long as the criteria are not violated. For example, in one case, the Corps of Engineers issued a dumping permit based on (1) pooling and averaging the results of bioassay mortality tests and (2) a 10 percent level for determining what mortality rate represents a significant undesirable environmental effect. A reviewing court upheld the permit because these interpretations of the permit criteria were not plainly erroneous or arbitrary and capricious.[8] Thus, so long as a permit decision is rational and does not violate the permit criteria, it will probably be upheld in the courts.

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[7] National Wildlife Federation v.Costle, 14 ERC 1680,1692 (D.C. Cir. 1980). The Court wanted EPA to explain why dredged materials were exempted from restrictions on oxygen-consuming constituents and microorganisms, and subject to less extensive testing procedures, less stringent site design criteria, and less stringent site evaluation procedures. Id., at 1694.

EPA's permitting authority covers the dumping of all types of materials into ocean waters. The Corps of Engineers, however, has partial authority over permits for the dumping of dredged materials. The Corps receives permit applications for dredged materials and reviews them using EPA's criteria for evaluation of materials. EPA, however, has final authority over all dumping permits.[9]

SUMMARY

In short, this statute declares all dumping prohibited unless EPA permits it, on the basis of criteria to be administratively established, taking into account its effects on "human health, welfare, or amenities, or the marine environment, ecological systems, or economic potentialities" (33 USC §1401(b) and the need for dumping. Dumping of those materials considered to have unreasonable adverse effects is prohibited.

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[8] National Wildlife Federation v. Benn, 491 F. Supp. 1234 (S.D.N.Y. 1980).

[9] Section 103, 33 USC §1413.

MARINE PROTECTION RESEARCH AND SANCTUARIES ACT -- REGULATORY REVIEW

INTRODUCTION

This review summarizes the regulations promulgated under Section 102 of the Marine Protection Research and Sanctuaries Act through January 1, 1981. The regulations cover the control and permitting of ocean dumping. The following topics are covered:

- Summary of Regulations--provides a brief condensation of the history and content of the regulations dealing with the dumping of both dredged and nondredged material in U.S. territorial seas.

- Permitting Criteria--describes the materials prohibited and allowed for ocean dumping, and the way in which these are classified and determined.

SUMMARY OF REGULATIONS

The Marine Protection and Research Sanctuaries Act (MPRSA) Secton 102 declared that "it is the policy of the United States to regulate the dumping of all types of materials into ocean waters and to prevent or strictly limit the dumping into ocean waters of any material which would adversely affect human health, welfare or amenities, or the marine environment, ecological systems, or economic potentialities".[1]

Regulations promulgated under this act reflect the comprehensive mandate given to EPA to regulate "all types of materials". Consequently, all material to be dumped is automatically prohibited unless the dumper can obtain a permit. The process and criteria by which an applicant can prove that ocean dumping is not only necessary, but will not have unacceptable adverse effects on the marine ecosystem, human health, or other uses of the ocean, is the substance of the regulations.

EPA first published ocean dumping regulations in 1973.[2] Since then, some major changes have been made. Exhibit 4-1 summarizes the regulatory history.

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[1] 33 USC §1401(b).

[2] 38 FR 28610 (Oct. 15, 1973) Final Rules.

EXHIBIT 4-1

REGULATORY CHRONOLOGY

1972	Marine, Protection, Research and Sanctuaries Act enacted
Spring 1973	EPA publishes interim permitting regulation, and interim criteria for the evaluation of permits
October 1973	Final Regulations promulgated (40 FR 28610, October 15, 1973)
March 1974	MPRSA amended to bring Act into full compliance with the International Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter (P.L. 93-254)
June, 1976	Proposed Revised Regulations and Criteria for Permitting published (41 FR 23544, June 18, 1976). Draft EIS on the permitting criteria issued (EPA, June 14, 1976) for public comment
October, 1976	EPA holds a technical workshop dealing wih the trace contaminant and dredged material criteria to obtain recommendations for revised criteria (October 19-20, 1976)
January, 1977	Final Revised Regulations and Criteria published (42 FR 2642, January 11, 1977)
November, 1977	MPRSA amended (P.L. 95-153) to prohibit all dumping of harmful sewage sludge after December 31, 1981
October, 1980	Final Regulations and Criteria published (45 FR 65942, October 3, 1980)

The MPRSA was amended in 1974 to agree procedurally and legally with the International Convention on the Prevention of Marine Pollution by Dumping of Waste and Other Matter. The regulations under MPRSA must be at least as stringent by law as the Convention[3]. The Convention lists several categories of prohibited and limited materials for ocean dumping in much the same way as U.S. ocean dumping regulations. However, the Convention does require special care and testing for very specific categories of waste constituents not directly mentioned in U.S. regulations, including constituents such as lead, chromium, organosilicon compounds, cynanides, and pesticides. Although U.S. regulations do not discuss these substances specifically, their effects would be measured in the required bioassay and bioaccumulation tests, as well as through the application of the Convention.

Final regulations published approximately one year after MPRSA was amended contain permitting criteria applicable to both (1) ocean dumping and (2) ocean discharges, which are regulated under Section 403(c) of the Clean Water Act (See 40 CFR 122).[4] Because of administrative problems, and because the criteria were primarily focused upon the dumping of transported waste materials, EPA published two sets of criteria, both revised, as separate regulations. Ocean discharges now require an National Pollutant Discharge Elimination System (NPDES) permit and must conform to ocean discharge criteria. These criteria, final rules, were promulgated in October, 1980.[5] The discharge criteria are designed to prevent "unreasonable degradation of the marine environment." The criteria require similar considerations as the ocean dumping criteria, including significant adverse changes in the biological community, the threat to human health through toxic and/or bioaccumulative wastes, and the esthetic, recreational, scientific, and economic effects of the discharge compared to its benefits.

In October 1977, a controversial amendment (P.L. 95-153) to MPRSA was enacted that prohibits disposal of harmful "sewage sludge" after December 31, 1981.[6] The amendment was introduced because of particular pollution problems along the East Coast, including the closing of beaches along Long Island

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[3] 33 USCA §1412(a).

[4] 42 FR 2462 (January 11, 1977), Final Revision of Regulations and Criteria.

[5] 45 FR 65942 (October 3, 1980), Final Rules.

[6] Public Law 95-153. Section 4 defines "Sewage sludge" as any "solid, semisolid, or liquid waste generated by a municipal wastewater treatment plant, the ocean dumping of which may unreasonably degrade or endanger human health, welfare, amenities or the marine environment, ecological systems, or economic potentialities."

and a massive fish kill on the Mid-Atlantic coast in 1976. There was also continuing concern by the Congress (Merchant Marine and Fisheries Committee, House of Representatives) that EPA was not enforcing MPRSA adequately.[7] The committee felt that EPA was overusing interim permits, not establishing firm phase-out dates for dumping, and continuing to permit materials unable to meet the environmental impact criteria. EPA opposed the amendment, saying that it was administratively inflexible and economically infeasible. Despite these objections, the amendment was passed. After December 31, 1981, no "harmful sewage sludge" may be dumped, and, as published in the regulations, no permits will be issued for materials that do not meet the environmental impact criteria.[8]

The controversy surrounding this mandate also stems from the municipalities involved: populous East Coast cities or counties, with severe fiscal problems, which must come up with alternative land disposal sites. The municipalities still operating under interim permits, only three in 1980, are being forced to curtail dumping or use designated dumpsites much farther out to sea than previously used. New York City, in fact, has brought suit against EPA, claiming that the environmental criteria are too stringent in light of data on dump sites collected by EPA and NOAA and the environmental and monetary costs of land-based methods. Although the dumping of sludge has many potential adverse effects, including heavy metal loading, degradation of coastal water quality through pathogens, and toxicity to marine organisms, the accumulating data from monitoring dumpsites may require changes in dumping limitations. Since the amendment bans only the dumping of "harmful" sewage sludge that may unreasonably degrade the marine environment or endanger human health, dumping may still be allowed after December 31, 1981 if the criteria upon which that determination is made are changed, or if some sludges can meet the present criteria.

CRITERIA FOR PERMITTING

EPA has set up a regulatory approach to ocean dumping with several levels of control, the ultimate purpose being "to regulate the dumping of all types of materials into ocean waters".[9] All materials to be dumped require a permit. Except for those wastes generally approved for dumping, all wastes must meet the environmental need, and economic and social impact criteria reviewed below. The burden of proof rests with the applicant to show that

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[7] U.S. Code Cong. and Admin. News 1977, p. 3262. Although the beach closings and fish kills were shown later not to be directly caused by sludge dumping, they still brought public attention to ocean pollution problems.

[8] 40 CFR 220.3(d).

[9] 33 USC §1401(b).

"the disposition of materials into the territorial seas or contiguous zone" (definition of dumping) "will not unduly degrade or endanger the marine environment".[10] The criteria described below, including the environmental impact criteria and other necesary criteria used to evaluate proposed dumping, are applied on a case-by-case basis from information available to the applicant, EPA, or the Corps of Engineers.

ENVIRONMENTAL IMPACT CRITERIA

These specific criteria form the basis for the applicant to show that the proposed disposal of either dredged or non-dredged material does not have significant adverse environmental impacts. EPA regulations evaluate materials by setting up five categories:[11]

1. Materials that are prohibited (40 CFR 227.5)
2. Materials that contain certain constituents prohibited except as trace contaminants (40 CFR 227.6)
3. Materials allowed only under certain limitations (40 CFR 227.7)
4. Wastes that may generally be appproved for dumping (40 CFR 227.2).
5. Dredged Materials (40 CFR 227.13).

1. Prohibited Materials. The ocean dumping of the following materials is prohibited and will not be approved for dumping under any circumstances:

- High-level radioactive wastes[12]

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[10] 40 CFR 220.2(e). "Dumping" is defined in the regulations as any disposition of material provided that it does not encompass several exceptions including: effluents from discharges covered by the Clean Water Act, Rivers and Harbor Act, or Atomic Energy Act of 1954, routine effluents from vessels; the construction of artificial islands or intentional placement of any device, oyster shells, fish wastes, or any other material for fisheries development.

[11] 40 CFR 227.5 - 227.13.

[12] 40 CFR 227.30. High-level radioactive wastes means the aqueous waste resulting from the operation of the first cycle solvent extraction system, or equivalent, and the concentrated wastes from subsequent extraction cycles, or equivalent, in a facility for reprocessing irradiated reactor fuel or irradiated fuel from nuclear power reactors. All other radioactive wastes must be properly containerized as defined in 40 CFR 227.11.

- Materials produced or used for radiological or biological warfare
- Persistent inert synthetic or natural materials which may float or remain in suspension in such a manner that might interfere with fishing, navigation or other uses of the ocean.
- Materials insufficiently described by the applicant to effectively evaluate the application on the basis of the environmental impact criteria.

2. Trace Contaminants. The prohibited materials above are relatively clear cut and easily distinguishable. Materials containing the constituents below, which are prohibited other than as trace contaminants, are more difficult to define and quantify:[13]

- Mercury and its compounds[14]
- Cadmium and its compounds
- Organohalogens, (for example:[15] DDT, Chloroform, methylchloride, PCBs, trichloroethylene, many others)
- Oil and greases

The term "trace contaminants" was used primarily to agree with the International Convention. The final regulations do not really define trace contaminants, they merely describe what is acceptable for ocean dumping:

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[13] 40 CFR 227.6

[14] Preamble to the Final Rules, 42 FR 2466 (January 11 1977). Mercury is an exception to the limiting permissible concentration explained below. Because mercury levels fluctuate, and because the marine water quality criteria are set near the lowest ambient levels observed, the mercury concentration may exceed the average normal ambient concentration, after initial mixing, by not more than 50% in the liquid phase.

[15] These are not listed in the ocean dumping regulations, but are examples taken from the list of criteria toxic pollutants designated at 40 CFR 401.15 pursuant to Section 307(a) of the Clean Water Act. Approximately half of this list are organohalogens.

> Those quantities that are in such form and amount that the dumping will not cause significant undesirable effects, including the possibility associated with their bioaccumulation in organisms.

The determination of "those quantities" rests on data that can predict the constituents' effects on the marine ecosystem. As stated in the preamble to the final rules: "The test to be applied on all wastes is the direct determination of the impact of these consitutents present in a waste on the marine ecosystem as measured by bioassy techniques."[16] This method is consistent with an ecosystem approach and yields a more accurate assessment of the materials impact than comparing total amounts of specific constituents with arbitrary ambient values. Bioassay and bioaccumulation testing, however, is a new field, at least for the suspended particulate and solid phases, and requires special guidelines and a case-by-case evaluation. Bioassay procedures are used to set the "limiting permissable concentration" that makes up the monitoring parameter for specific constituents.

The trace contaminants listed above, or any other toxic waste, as directed in 40 CFR Section 227.8 (Limitations on the disposal of toxic wastes), cannot exceed its "limiting permissable concentration". The definition of limiting permissable concentration is central to the application of the regulations.[17] Liquid, suspended particulates and solid phases of the material to be dumped each have a limiting permissable concentration for the particular constituent determined by its effect on the marine environment. The application of limiting permissible concentation is shown in Exhibit 4-2.

For those materials listed as prohibited other than trace contaminants, the specific bioassay requirements do not apply if the applicant can demonstrate that the constitutents are present in a form that is non-toxic and non-biocumulative to the marine environment, or will be rapidly rendered so in the marine environment by biological or chemical degradation. However, the presence of these materials cannot make edible marine organisms unpalatable, or endanger the health of humans, domestic animals, fish, shellfish, or wildlife.[18] For any waste materials with uncertain or unqualified effects the bioassay and bioacummulative tests are required.

As demonstrated by the definition above, EPA has great leeway in identifying trace contaminants and their allowable concentrations. For example, as indicated in the regulations, if EPA or the Corps of Engineers has "resonable

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[16] Preamble to the Final Rules, 42 FR 2462-2467 (January 11, 1977).

[17] Definition of limiting permissible concentration (LPC) 40 CFR 227.27.

[18] 40 CFR 227.6(f).

EXHIBIT 4-2

LIMITING PERMISSIBLE CONCENTRATION

Phase	Concentration of Waste Constituent, after Initial Mixing[1]
Liquid	May not exceed applicable marine water quality criteria.[2] If there are no applicable criteria, will not exceed 0.1 of a concentration shown to be acutely toxic to appropriate sensitive marine organisms.[3]
Suspended particulates and solids	Will not cause unreasonable acute or chronic toxicity or accumulation of toxic materials. This is determined through bioassay and bio-accumulation tests using appropriate sensitive marine and benthic organisms.

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[1] 40 CFR 227.20 defines initial mixing based on a mathematical or other theoretical model.

[2] 40 CFR 227.3 defines applicable marine water quality criteria as the standards published by EPA in "Quality Criteria for Water" as published in 1976, with subsequent amendments.

[3] "Appropriate sensitive marine organisms" are explained and specified at 40 CFR 227.31 with the definition of limiting permissable concentration. The factor of 0.1 is a standard figure used to extrapolate laboratory results to approximate field conditions. If there is field data that supports the use of a different toxicity factor, then a factor different than 0.1 will be required. EPA has published, and is in the process of revising, bioassay manuals for both dredged and non-dredged materials that delineate the exact procedures.

cause to believe" that a material proposed for ocean dumping contains carcinogens, mutagens, or teratogens which are not covered in the criteria, then they may require special studies before the issuance of a permit.[19] Potential toxic constituents are dealt with on a case-by-case basis, following bioassay procedures outlined in manuals published by EPA and the Corps of Engineers for dredged, municipal, and industrial wastes. These manuals, as well as the criteria, are in the process of being revised.

3. Other limited materials. Certain constituents are also limited in their concentrations and impacts. These materials are as follows:[20]

- Liquid waste constituents immiscible or slightly soluble in water, such as benzene, xylene, carbon disulfide, and toluene, may be present only below their solubility limits in seawater, as long as they do not interact with ocean water to form insoluble materials.

- Radioactive wastes, if not prohibited as high-level radioactive waste, must be safely containerized.[21]

- Wastes containing living organisms are prohibited if the organisms would endanger human or domestic animals health.

- Highly acidic or alkaline wastes require special care. After initial mixing, the waste cannot change the total acidity or alkalinity of the ocean water by more than 10 percent.

- Biodegradable wastes which consume oxygen may be dumped only in quantities which will not depress normal dissolved oxygen levels by more than 25%.

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[19] 40 CFR 227.6(d).

[20] 40 CFR 227.7.

[21] 40 CFR 227.11 describes the requirements for containerized wastes. The most prominent requirement is that the containers must last as long as the material takes to radiodecay. Additionally, the material, if it does leak or escape, may only cause short term localized effects. Because of the lack of proper containers, and the long term effects of radioactivity, no dumping of radioactive wastes is allowed at this time.

- Insoluble wastes (such as scrap or large quantities of inert materials) may not be dumped in quantities that might interfere with other uses of the ocean such as fishing or swimming.

4. Generally Harmless Wastes. Wastes that may generally be approved consist primarily of certain classes of dredged materials that are described below. Other types of materials usually approved of are small quantities of materials believed to be harmless, or special categories such as burial-at-sea.

5. Dredged Materials. Because of the quantities and types of materials generated by dredging, they are treated somewhat differently than municipal or industrial wastes.[22] Dredged materials included in the following categories do not require further testing and are generally approved of for dumping:[23]

- sand, gravel, or other bottom material larger than silt;
- material dredged for beach nourishment or restoration;
- material that is substantially the same as the substrate as long as there are no known historical sources of pollution at the dredging site.

Most dredged materials (approximately 70%), are included in these three categories. All other materials require further testing and characterization, including the bioassay tests required for municipal and industrial wastes.

NEED AND IMPACT CRITERIA

Besides the environmental impact criteria, the applicant must also meet several other sets of criteria that show the necessity for dumping and the potential adverse effects on other uses of the ocean. These are not just physical criteria, but deal with policy options. If the materials proposed for ocean dumping meet the environmental impact criteria, then the permit will be issued unless:[24]

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[22] Litigation has established EPA's authority to promulgate different criteria for dredged and non-dredged materials but the case also held that EPA had not adequately explained why dredged materials should be subject to less stringent requirements. National Wildlife Federation v. Costle, 11 ERC 1680, (D.C. Cir. 1980).

[23] 40 CFR 227.13.

[24] 40 CFR 227.2.

- There is no need for ocean dumping. The applicant must show that he has considered other options (e.g., landfill, recycling, incineration, etc) and the environmental and economic costs of each. (40 CFR 227.14)
- The dumping of the material would cause "unacceptable adverse effects" on economic, aesthetic or recreational values. These would include the potential for affecting beaches or shorelines, commercial fishing, or other municipalities or industries. (40 CFR 227.17)
- The proposed disposal of the material would have "unacceptable adverse effects" on other uses of the ocean and coastal areas; for example, scientific research or oil and gas exploration. (40 CFR 227.20)

If the proposed disposal of materials does not meet any one of the above considerations, or the environmental impact criteria (only before December 31, 1978), the applicant may apply for an interim permit. Besides the limitations on the type of materials dumped under interim permits, the applicant must also show that the need for ocean dumping is greater than the potential adverse effects on economic, aesthetic, or recreational values, or the marine environment.

The purpose of these other criteria, each described in more detail in a section of the regulations, is to insure that there is consideration of economic and social factors in the decision to allow ocean dumping. In general, they apply another set of restrictions to the permitting process, that is: if the materials meet the environmental impact criteria plus if the dumping meets the criteria described above, then a permit will be issued for dumping.

DUMPING PERMIT PROGRAM

The ocean dumping program consists of site designation, permitting, and surveillance and enforcement. Site designation must take into account the geographic placement of the site, waste dispersal characteristics, and interference with other uses of the ocean.[25] The parameters used in designating and monitoring dumpsites for both dredged and non-dredged material include, at a minimum: location, depth, currents, water quality, potential accumulation of dumped constituents, historical uses of the dumpsite, and the composition of the biota present. The background or ambient levels of certain constituents, particularly heavy metals, are especially important since these values will affect the limitations on added increments from dumping. Both EPA and NOAA (which administers Title II of MPRSA, that calls for an ocean research and monitoring program) take on the burden of researching, designating and monitoring dump sites. Surveillance, enforcement notice and safe waste transport responsibilities are given to the Coast Guard.

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[25] 40 CFR 228.

Although the criteria and procedures for designating dump sites and obtaining dumping permits are different, the two categories are inseparable, considering the interaction between dumped material and the marine environment. Dumping permits are issued by both the Corps of Engineers and EPA for dredged and non-dredged material, respectively. Six categories of permits cover disposal of materials in the ocean:

> (1) General, (2) Special, (3) Interim, (4) Emergency, (5) Research and (6) Incineration at Sea.

Applications for permits must include all information necessary to evaluate the application. At a minimum, they must include, besides general information, a detailed physical and chemical analysis of the waste materials, including results of bioassay or other tests required to apply the impact criteria. The application to EPA or the Corps of Engineers must also include the following: the proposed dumpsite, times and amounts of material dumped, a description of the way in which this material has previously been disposed of, identification of the process or activity generating the wastes, the method of release of the materials, and an assessment of the environmental impact of the proposed dumping.[24]

General permits are issued for disposal of small amounts of generally harmless wastes. Holders of special permits, which include municipal, industrial and dredged material dumpers, must meet the environmental impact criteria. Interim permits, good for only one year, must indicate either a compliance schedule showing a phase out of dumping or compliance with the environmental impact criteria by 1981. Most dumpers of industrial wastes and municipal sewage sludge have been operating under interim permits since the revised regulations of 1977 due to their inability to meet the criteria. An interim permit, which may not be issued to any new dumpers, may not include any prohibited materials or those classified as trace contaminants only. Additionally, the dumper must demonstrate a need for dumping and the potential adverse effects on other uses of the ocean. The other three classes of permits, emergency research, and incineration at sea, are issued on a limited, case-by-case basis.

Dredged material permits administered by the Corps of Engineers (same categories as above), are issued for private firms, and state and local agencies. Approximately ninety-five percent of the dredged material generated in the U.S. is from Corps of Engineers projects.[27] Although the Corps cannot issue permits to itself, under the 1977 amendment and Corps agency policy, Corps projects' dredging spoil must go through the same critical process as private firms and muncipalities. Dredged material is dumped at sites designated by EPA specifically for dredged material.

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[24] 40 CFR. 225.1.

SUMMARY

The greatest dangers to human health and welfare from ocean dumping are the potential effects of bioaccumulation and ingestion of toxics or carcinogens through the human food chain. Examples would include the accumulation of heavy metals like mercury and its compounds in fish and shellfish, the contamination of ocean water and seafood with organohalogens like PCBs or pesticides, or the bioaccumulation of carcinogens. Other materials strictly limited in the regulations that might endanger human health include possible pathogenic organisms or radioactive wastes. The regulations are also obviously geared to protecting the marine ecosystem and economic potentialities as well as human health: oxygen consumptive wastes and highly acidic or alkaline wastes can disrupt the natural nutrient cycles, while the dumping of oil has obvious effects on fishing and recreation. In fact, the bioassay testing approach favors a strict and careful assessment of the possible effects of dumping. The regulations also give tremendous latitude to EPA to evaluate each permit on a case-by-case basis, and to change its evaluations with updated scientific evidence. Flexibility, however, might have to be sacrificed to impose consistency on the implementation of the criteria. For example, the Corps of Engineers analysis of dredged materials should agree with EPA's analysis of municipal and industrial wastes because they are based on the same criteria. Similarly, each waste should be rated consistently for a range of disposal options--both ocean discharges and ocean dumping. The need for consistency might eventually require a more specific designation of limitations and allowances.

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[27] Council of Environmental Quality, Environmental Quality Yearbook, 1979 p. 164.

RESOURCE CONSERVATION AND RECOVERY ACT--STATUTORY REVIEW

INTRODUCTION

The Resource Conservation and Recovery Act (RCRA) became law on October 31, 1976.[1] Among its objectives is the protection of public health and the environment by authorizing the regulation of the treatment, storage, transportation, and disposal of hazardous wastes which can have adverse effects on the environment.[2] The Congress explicitly found that the disposal of hazardous waste without careful planning and management "can present a danger to human health and the environment."[3] For example, open dumping contaminates drinking water from underground and surface supplies and pollutes the air and land as well.[4] Congress also found that hazardous waste presents "special dangers to health and requires a greater degree of regulation than does non-hazardous solid waste."[5]

Subtitle C of the Resource Conservation and Recovery Act (RCRA) establishes the outlines of a comprehensive program for regulating hazardous wastes. Section 3001 directs EPA to identify the characteristics of hazardous wastes and to list specific hazardous wastes which will be subject to regulation. Sections 3002 and 3003 direct EPA to establish standards for generators and transporters of hazardous wastes, including the use of a manifest system to track shipments, require proper labels and containers, etc. Other sections address standards for disposal facilities, permits, and state-administered programs. The goal was to provide "cradle-to-grave" regulation. Since the journey from "cradle" (i.e., the "generator" of the waste) to "grave" (i.e., disposal site) often involves transportation, RCRA directed that a manifest system be used to track shipments.

Congress' "overriding concern" in enacting Subtitle C was to address the risks posed to the population and the environment by the disposal of hazardous wastes. Congress was particularly concerned about wastes which are "harmful, toxic, or lethal" because of their chemical composition or "longevity."[6]

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[1] Public Law 94-580, 42 USC §6901 et seq.

[2] RCRA Section 1003(4), 42 USC §6902.

[3] RCRA Section 1002(b)(2), 42 USC §6901.

[4] RCRA Section 1002(b)(4).

[5] RCRA Section 1002(b)(5).

[6] H.R. No. 94-1491(I), p. 3.

DESIGNATION AUTHORITY OF SECTION 3001

The statute defines "hazardous wastes" broadly to include any waste or combination of wastes which "because of its quantity, concentration, or physical, chemical, or infectious characteristics may:

> (A) cause or significantly contribute to an increase in mortality or an increase in serious irreversible, or incapacitating reversible, illness; or
>
> (B) pose a substantial present or potential hazard to human health or the environment when improperly treated, stored, transported, or disposed of, or otherwise managed.[7]

Criterion (B) evidences a risk-averse, preventive goal by including materials which "may" pose a substantial "potential" hazard when "improperly" treated. The statutory language seems to imply that Congress did not want the EPA to exempt any hazardous wastes from regulation on the assumption that proper management would obviate potential hazards.

RCRA specifies a two-step procedure which EPA must follow in designating hazardous wastes. First, EPA must promulgate criteria for identifying hazardous waste characteristics; second, EPA must identifiy those characteristics and list the hazardous wastes. The criteria are to be the standard of judgment for determining hazardous waste characteristics and for listing hazardous wastes. According to the legislative history, Congress wanted the EPA to first develop the criteria and then identify characteristics and list specific hazardous wastes afterwards.[8] The listed wastes must satisfy the statutory definition described above.[9]

RCRA directs EPA to take into acount toxicity, persistence, and degradability in nature; potential for accumulation in tissue; and other factors such as flammability, corrosiveness, and other hazardous characteristics in developing the listing criteria.[10] The House Report states that Congress wanted EPA to identify specific hazardous wastes that pose a hazard to human health and the environment and anticipated the identification of two basic types of substances:

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[7] RCRA Section 1004(5), 42 USC §6903(5). One court has stated in dicta that "It seems clear that [this definition] would include nuclear waste." City of Philadelphia v. N.J., 10 ERC 1312,1313 (N.J. Sup. Ct., 1977).

[8] H.R. No. 94-1491(I), p. 25.

[9] RCRA Section 3001, 42 USC §6921.

[10] RCRA Section 3001(a), 42 USC §6921(a).

(1) those which are hazardous in their elemental and most common form, regardless of concentration [sic]; and

(2) those which when present in sufficient concentration or when mixed with other substances constitute hazardous wastes.[11]

The use of designation criteria means that even if a waste is not listed or identified as hazardous in the regulations, it is nevertheless subject to the hazardous waste regulations so long as it meets the general criteria. These are discussed in more detail in the regulatory review.

The 1980 Amendments to RCRA (P.L. 96-482) added special provisions relating to "drilling fluids, produced waters, and other wastes associated with the exploration, development, or production of crude oil or natural gas or geothermal energy." The Amendments require EPA to conduct a study and report on the "adverse effects, if any" on "human health and the environment, including, but not limited to, the effects of such wastes on humans, water, air, health, welfare, and natural resources and on the adequacy of means and measures currently employed ... to dispose of and utilize such wastes and to prevent or substantially mitigate such adverse effects." (Section 8002(m)) On the basis of the study, EPA is to determine whether regulation is warranted. In addition, EPA is authorized by the 1980 Amendments to prescribe regulations to prevent radiation exposure which "presents an unreasonble risk to human health" from the use in construction or land reclamation of (1) solid waste from the extraction, beneficiation, and processing of phosphate rock or (2) overburden from the mining of uranium ore. (§3001(b)(3)(A)(iii))

COORDINATION WITH OTHER ACTS

RCRA contains specific language to assure coordination and consistency with other EPA programs as well as other agencies, notably the Department of Transportation. This is essential in view of the broad authority to regulate hazardous wastes granted by RCRA.

The Office of Management and Budget (OMB) took the position in its comments to Congress that a substantial portion of hazardous wastes are already subject to control through the underground injection provisions of the Safe Drinking Water Act.[12] Congress nevertheless enacted RCRA to respond to the pollution of surface waters, croplands, and pasturelands by runoff; the pollution of air from evaporation, sublimation, wind erosion, and improper incineration; and dangers from fires and explosions in addition to the contamination of groundwater by leachate.[13] Congress explicitly instructed EPA to integrate the administration and enforcement of the provisions of RCRA with its other authorities.[14] Congress also specified that RCRA should not be construed to apply to any substance which is subject to the Federal Water Pollution Control Act, the Safe Drinking Water Act, the Marine Protection, Research and Sanctuaries Act, or the Atomic Energy Act except to the extent that RCRA regulations are "not inconsistent" with the requirements of those acts.[15]

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[11] H.R. No. 94-1491(I), p. 25.

[12] H.R. No. 94-1491(I), p. 81.

Similarly, in assigning EPA the responsibility to designate "hazardous wastes" and to develop standards for transporting those wastes, Congress took into account the Department of Transportation's long-standing regulation of hazardous materials transport. EPA was directed to consult with the Department of Transportation before developing transportation standards for hazardous wastes.[16] In addition, for any hazardous waste identified or designated for regulation by EPA which is also subject to DOT rules under the Hazardous Materals Transportation Act, Congress directed that EPA rules shall be "consistent" with the DOT requirements.[17] Furthermore, the legislative history of RCRA indicates that Congress expected EPA to establish a manifest system for tracking hazardous waste movements "in cooperation with" the Department of Transportation. Congress authorized EPA to make recommendations to DOT of whether or not particular wastes were hazardous in transportation.[18]

CASELAW

Following the issuance of EPA's rules for hazardous waste management, fifty separate lawsuits were filed challenging the rules.[19] The legal challenges were consolidated in the U.S. Court of Appeals for the District of Columbia Circuit early in October, 1980 and, with many of the industrial plaintiffs seeking stays of the rules while suits are pending, it may be a year or two before the cases are decided. As of January 1, 1981, none of the issues had been judicially resolved.

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[13] Ibid., p. 89.

[14] Clean Air Act; Federal Water Pollution Control Act; Federal Insecticide, Fungicide, and Rodenticide Act; Safe Drinking Water Act; Marine Protection, Research and Sanctuaries Act. RCRA Section 1006(b), 42 USC §6905(b).

[15] RCRA Section 1006(a), 42 USC §6905(a).

[16] Section 3003(a).

[17] Section 3003(b).

[18] HR No. 94-1491(I), p. 6 (see also p. 27: EPA "is required to coordinate these regulations with those of the Secretary of Transportation regarding transportation of hazardous materials.").

[19] The suits were filed by one environmental group seeking to sharpen the requirements and thirty-seven companies and trade associations seeking to overturn them. 3 The National Law Journal pp. 1, 24-5 (November 10, 1980).

RESOURCE CONSERVATION AND RECOVERY ACT--REGULATORY REVIEW

INTRODUCTION

This section summarizes the identification and listing of hazardous wastes promulgated under the authority of Section 3001 of the Resource Conservation and Recovery Act. It is organized in the following manner:

- Summary of Regulations--provides a brief background on the regulatory history and approach to hazardous waste designation.
- Criteria for Designation--presents EPA's approach to and criteria for designating of chemicals as hazardous wastes.
- List of Chemicals Designated--includes the list of chemicals designated as of January 1, 1981, as hazardous wastes, and discusses issues relating to the identification of the chemicals.

SUMMARY OF REGULATIONS

Hazardous wastes are regulated by EPA under Subtitle C of the Resource Conservation and Recovery Act (RCRA) of 1976.[1] Subtitle C mandates EPA to establish a "cradle-to-grave" management system for hazardous wastes. The centerpiece of this system is Section 3001, "which requires EPA to identify and list those solid wastes which must be managed as hazardous wastes according to the standards established by EPA under Sections 3002 through 3005."[2]

Section 3001 entails a two-step process. Under Section 3001(a), EPA must develop criteria for identifying the characteristics of hazardous waste and for listing hazardous wastes. Under Section 3001(b), EPA must then actually identify specific characteristics of hazardous waste and list particular hazardous wastes. Wastes which are listed as hazardous are subject to Subtitle C regulations of recordkeeping, management, etc.

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[1] 42 USC §6901 et seq. See Statutory Review, above.

[2] Introduction to Final Rule and Interim Final Rule on Hazardous Waste Management Systems: Identification and Listing of Hazardous Waste. 45 FR 33084 (May 19, 1980), p. 33085.

EPA developed its Subtitle C regulations over the course of 1977 and 1978. Exhibit 5-1 summarizes the regulatory history of hazardous wastes regulations through January 1, 1981. EPA's final rules differ from the proposed rules in their organization, and the final rules clarify many provisions of the proposals. Some substantive changes were made to the regulations, based on the extensive comments received on the proposed rules; relevant changes are noted, where applicable, in the next section.

The final regulations define solid waste as "any garbage, refuse, sludge or any other waste material",[3] and they define hazardous waste as any solid waste that appears on the list of hazardous wastes and/or that exhibits any of the defined characteristics of hazardous waste.[4]

CRITERIA FOR DESIGNATION

EPA used two mechanisms for classifying wastes as hazardous: (1) identifying characteristics which make the waste hazardous, and (2) identifying criteria for listing certain wastes directly. Although the two mechanisms overlap, we discuss each separately.

Identification of Characteristics

EPA developed two criteria in order to identify characteristics that would cause solid wastes to be defined as hazardous wastes. The criteria are:

1. If the characteristic exhibited by the solid waste may

    (i) "cause, or significantly contribute to, an increase in mortality or an increase in serious irreversible, or incapacitating reversible, illness; or

    (ii) pose a substantial present or potential hazard to human health or the environment when it is improperly treated, stored, transported, disposed of or otherwise managed; and

2. The characteristic can be:

    (i) measured by an available standardized test method which is reasonably within the capability of generators of solid waste or private sector laboratories that are available to serve generators of solid waste; or

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[3] 40 CFR 261.2(a).

[4] 40 CFR 261.3(a).

EXHIBIT 5-1

REGULATORY CHRONOLOGY

Date	
1976	RCRA enacted.
1977-1978	EPA holds meetings with agencies and organizations to obtain suggestions.
Fall 1978	EPA sued under RCRA Section 7004 to force promulgation of final 3001 regulations by a date certain. [*State of Illinois v. Costle*, 12 ERC 1597 (D.D.C. 1979)].
December 18, 1978	EPA proposes hazardous waste regulations (43 FR 58949).
1979	Public hearings.
January 3, 1979	Court orders EPA to issue final 3001 regulations by December 31, 1979.
August 22, 1979	EPA proposes supplemental list of hazardous wastes (44 FR 49402).
December 18, 1979	Court order modified to have EPA try to meet April 1980 promulgation date.
May 19, 1980	EPA promulgates final and interim final rules for hazardous waste lists; proposes listing of 11 additional wastes (45 FR 33084).
July 16, 1980	EPA promulgates interim final rules for an additional 18 wastes, defers action on six wastes, proposes listing for seven other wastes (45 FR 47835).
October 30, 1980	EPA delists eight waste streams (final action), amends the EP toxicity characteristic as it applies to chromium (proposed rule), and temporarily excludes certain wastes from hazardous waste status (interim final rule) (45 FR 72024).
November 12, 1980	EPA finalizes the listing of 80 hazardous wastes; defers action on five others (45 FR 74884).
January 16, 1981	EPA finalizes list of 13 additional hazardous wastes, deleted several other wastes, and deferred action on others (46 FR 4614).

(ii) reasonably detected by generators of solid waste through their knowledge of their waste."[5]

The first criterion thus requires that the characteristics cause the waste to be hazardous within the meaning of the statutory definition of hazardous waste. The second criterion recognizes that the characteristics must be easily measurable by the generators who have primary responsibility for determining whether their wastes exhibit the hazardous characteristics. Both criteria must be met for the characteristic to be defined as hazardous.

EPA identified the following four characteristics of hazardous waste which meet the two criteria discussed on the previous page:[6]

(1) ignitability--posing a fire hazard during routine management;

(2) corrosivity--ability to corrode standard containers, or to dissolve toxic components of other wastes;

(3) reactivity--tendency to explode under normal management conditions, to react violently when mixed with water, or to generate toxic gases; and

(4) extraction procedure (EP) toxicity (as determined by a specific extraction procedure)--presence of any of 14 specified toxic materials within the waste at levels greater than the maximum concentration specified in the regulation. The characteristic of EP toxicity is intended as a model of a prevalent form of waste mismanagement--the co-disposal of toxic wastes in an actively decomposing municipal landfill which overlies a groundwater aquifer. The EP test, which is innovative in character, is designed to simulate the physical processes which would occur in an actual landfill.[7]

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[5] 40 CFR 261.10.

[6] 40 CFR 261.21-261.24.

[7] Preamble to the Final Rules, pp. 33110-1. The extraction procedures and test methods are specified in Appendix II to the Final Rules. The 14 chemicals and their concentrations were specified in the National Interim Primary Drinking Water Standards. EPA was unable to extend the extraction procedure to additional contaminants because no other chronic exposure threshold levels relating to drinking water consumption have been established for other contaminants.

Each of the four characteristics is described in the regulations in terms of specific measurable properties. Any waste exhibiting one or more of these characteristics is defined by 40 CFR 261.20(a) as a hazardous waste. In a few cases, wastes with a hazard characteristic are explicitly listed in 40 CFR 261.31 and 261.32. The large majority of wastes with these characteristics, however, are defined as hazardous by rule.

Exhibit 5-2 shows the maximum concentration of 14 contaminants above which a waste has the characteristic of EP toxicity:

EXHIBIT 5-2

EP TOXICITY

Contaminant	Maximum Concentration (milligrams per liter)
Arsenic	5.0
Barium	100.0
Cadmium	1.0
Chromium (VI)[a]	5.0
Lead	5.0
Mercury	0.2
Selenium	1.0
Silver	5.0
Endrin	0.02
Lindane	0.4
Methoxychlor	10.0
Toxaphene	0.5
2,4-D	10.0
2,4,5-TP Silvex	1.0

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[a] Proposed amendment, 45 FR 72029, October 30, 1980.

EPA had originally intended to also include as characteristics of hazardous waste: organic toxicity, carcinogenicity, mutagenicity, teratogenicity, bioaccumulation potential, and phytotoxicity. Because EPA later considered the available test protocols for measuring these characteristics to be either insufficiently developed or too complex, in its final rules the Agency decided to directly list toxic constituents known to have the properties of carcinogenicity, mutagenicity, etc.

Criteria for Listing Hazardous Wastes

EPA developed three main criteria for listing hazardous wastes. The first criterion is that the waste exhibits any of the four characteristics of hazardous waste outlined above. Secondly, wastes that are acutely hazardous are listed. These are wastes that EPA considers to be so acutely hazardous that, unlike most wastes, "they can be considered to present a substantial hazard whether improperly managed or not.[8] The third criterion involves wastes that contain designated toxic constituents which "have been shown in reputable scientific studies to have toxic, carcinogenic, mutagenic or teratogenic effects on humans or other life forms and include such substances as those identified by the Agency's Carcinogen Assessment Group."[9]

Using these criteria for directly listing hazardous waste, EPA compiled a list of chemicals considered to be either acutely hazardous or toxic, which are or will be subject to regulation. This list, referred to as Appendix VIII, contains over 350 hazardous constituents;[10] the presence of any of these constituents in a waste is sufficient to list the waste unless after consideration of certain designated factors, EPA concludes the waste is not hazardous. The factors designated are:

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[8] Preamble to the Final Rules, p. 33106. [Emphasis added.] Specifically, the regulation states that such a waste "has been found to be fatal to humans in low doses or, in the absence of data on human toxicity, it has been shown in studies to have an oral LD50 toxicity (rat) of less than 50 milligrams per kilogram, an inhalation LC50 toxicity (rat) or less than two milligrams per liter, or a dermal LD50 toxicity (rabbit) of less than 200 milligrams per kilogram or is otherwise capable of causing or significantly contributing to an increase in serious irreversible, or incapacitating reversible, illness. (Waste listed in accordance with these criteria will be designated Acute Hazardous Waste.)" (40 CFR 261.11(a)2). These wastes are "so potentially lethal as to be considered poisonous or acutely toxic", and include wastes such as explosives which meet the statutory definition of hazardous waste.

[9] Preamble to the Final Rules, p. 33107.

[10] Note that in using the criteria for listing, EPA actually identifies specific chemicals to be regulated. This is in contrast to EPA's identification of hazard characteristics which cause wastes to be listed as hazardous by general rule. Appendix VIII, with the list of chemicals to be regulated, is used by the Agency in three ways in the final rules: (1) as the basis for listing specific waste streams in 261.31 and 261.32; (2) as the basis for listing acutely hazardous wastes in 261.33(e); and (3) as the basis for listing toxic wastes in 261.33(f). Appendix VIII itself is not a regulation.

(i) The nature of the toxicity presented by the constituent.

(ii) The concentration of the constituent in the waste.

(iii) The potential of the constituent or any toxic degradation product of the constituent to migrate from the waste into the environment under the types of improper management considered in (vii) below.

(iv) The persistence of the constituent or any toxic degradation product of the constituent.

(v) The potential for the constituent or any toxic degradation product of the constituent to degrade into non-harmful constituents and the rate of degradation.

(vi) The degree to which the constituent or any degradation product of the constituent bioaccumulates in ecosystems.

(vii) The plausible types of improper management to which the waste could be subjected.

(viii) The quantities of the waste generated at individual generation sites or on a regional or national basis.

(ix) The nature and severity of the human health and environmental damage that has occurred as a result of the improper management of wastes containing the constituent.

(x) Actions taken by the other governmental agencies or regulatory programs based on the health or environmental hazard posed by the waste or waste constituent.

(xi) Such other factors as may be appropriate.[11]

The lists of hazardous waste and related substances are discussed in detail in the next section of this paper. Before moving on to the lists, we briefly discuss a few important points about the criteria outlined here. To follow the discussion more clearly, please refer to Exhibit 5-3 on the next page, which distinguishes among the various components of the system.

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[11] 40 CFR 261.11(a)3).

EXHIBIT 5-3

WASTES DESIGNATED UNDER RCRA

Mechanism for Regulation	What Wastes Are Involved	How They Appear in The Final Rules
Identification of Characteristics (RCRA Section 3001b)	4 characteristics identified: ignitability, corrosivity, reactivity, EP toxicity (14 constituents) (40 CFR 261 Subpart C)	Some wastes with these properties are explicitly listed in 261.31 and 261.32. Any other waste that has any of these characteristics is defined as hazardous.
Criteria for Listing: (RCRA Section 3001a)	(40 CFR 261.11)	
(1) Wastes with the 4 characteristics above	See above	See above
(2) "Acute Hazard"	Fatal to humans in low doses or otherwise extremely toxic however they are managed. Usually only pure chemicals will meet this definition, not constituents in a waste. Examples of "acutely hazardous waste" are dieldrin, phosgene, and cyanides.	Provisions apply only to pure chemicals and associated containers, etc. A list of these chemicals is contained in 261.33(e), and they are subject to regulation in very small quantities. (Note that most of these chemicals are drawn from Appendix VIII.)
(3) "Toxicity"	Carcinogenic, mutagenic, teratogenic, phytotoxic, organically toxic, or having potential for bioaccumulation. Examples of "toxic waste" are toluene, benzene, saccharin, formaldehyde.	Chemicals with these properties appear in Appendix VIII. They are regulated in two ways: (1) in Sections 261.31 and 261.32, which list specific hazardous waste streams and processes; and (2) in 261.33(f), which lists pure chemicals that are hazardous wastes if discarded.

As discussed above, the criteria for listing hazardous wastes reflect a change in EPA's emphasis from the strategy planned at the time of the proposed rules. Because EPA decided that the characteristics of hazardous waste would have to be readily measurable, the Agency needed an independent basis for capturing hazardous waste that could not be suitably tested by generators. EPA, therefore, revised its use of the listing mechanism from a supplementary function that would provide certainty about which wastes were hazardous, to a major function in the process of hazardous waste determination.

In its final rules, EPA relies on the listing mechanism to capture toxic wastes containing constituents believed to be carcinogenic, mutagenic, etc., as well as the acutely hazardous wastes. This approach entails a shift in the burden of identifying and evaluating these wastes onto EPA rather than the generators. EPA believes that the use of direct listing, coupled with provisions for rebuttal of the listing based on several factors, and accompanied by a delisting procedure, ensures a flexible and suitable approach.

The two approaches of identification of characteristics and criteria for listing differ in the degree of discretion retained by the Agency. This affects the emphasis EPA gives to waste constituent migration and environmental fate in the two approaches. As noted, the use of direct listing (for example, for substances which are carcinogenic) actually involves a more flexible approach, because each such waste is evaluated individually and mitigating factors can be considered in determining hazard. Because of this, EPA concentrated in its list on the composition of the waste, feeling that other mitigating factors such as migration potential which might render the waste hazardous, could be considered individually and by means of the delisting procedure. In the characteristics, on the other hand, there is no room for such flexibility because the tests for characteristics constitute a final determination of hazard. EPA, therefore, attempted to incorporate migration potential directly into the tests for the EP toxicity characteristic.[12]

In the course of regulatory development, EPA considered and then rejected two different approaches to determining the scope of regulatory coverage. The first was to base a determination that a waste is hazardous on the quantity of waste under consideration. However, the Agency found that no assessments could be made for most wastes that would take into account the possible exposures of the waste as well as the intrinsic hazard of the waste. That is, the Agency could not define de minimis quantities below which a waste would not be hazardous under Section 1005(5) of RCRA, without knowing the particular management system for the waste and the consequent exposure and risk patterns.

Secondly, EPA considered using the degree of hazard presented by a particular waste to establish different levels or types of controls. The objectives of such a system would be to implement the Subtitle C program more efficiently by establishing regulatory priorities, and to reduce the economic burden imposed on generators of relatively low hazard wastes. As suggested by a large number of commenters, the degree of hazard classification would ultimately relate to the health or environmental effects of the waste, and could be based on the chemical and physical properties of the waste and/or on the way the waste is managed. EPA found the degree of hazard system "conceptually appealing," but believes that neither the information nor the techniques exist to adequately distinguish the many hazardous wastes into appropriate categories. EPA maintains that in a variety of ways, its regulations do achieve the objectives of a degree of hazard system. One example cited is the very low exclusion limits established for acutely hazardous chemicals.[13]

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[12] Preamble to the Final Rules, p. 33107.

LISTS OF HAZARDOUS WASTES

This section discusses:

- naming and identification conventions used for listed wastes;
- test methods;
- concentration and quantity limits; and
- exclusions, deferred actions, delisting.

Because of the complexity and overlap in the lists and appendices promulgated by EPA, we have summarized some of the relevant information in Exhibit 5-4. There are basically two types of wastes being regulated here: (1) specific waste streams and processes which contain hazardous constituents or which have any of the four characteristics of hazard (261.31, 261.32); and (2) discarded pure chemical products and associated materials which might be discarded because the product did not meet the required specifications, or because inventories were being reduced, or because the product line had changed. Two lists are given here: 261.33(f) has toxic chemicals which are regulated at the same exclusion level (under 1000 kg/mo) as other hazardous wastes. 261.33(e) has acutely hazardous chemicals, regulated at very small quantities. Note that these chemicals are not listed as constituents of hazardous waste, but as wastes themselves.

An example of how these lists of chemicals and waste interrelate should help to clarify the system.

Example: Acrylonitrile.

Acrylonitrile is a hazardous constituent appearing in Appendix VIII. The actual chemical product acrylonitrile if discarded or intended to be discarded,

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[13] Preamble to 40 CFR Parts 264 and 265, pp. 33164-66.

EXHIBIT 5-4

EPA	List	Comments	Hazardous Waste Numbers
261.31	Hazardous waste from non-specific sources	Wastes which are listed as hazardous because they are ignitable, corrosive, reactive, EP toxic, acute hazardous, and/or toxic. Based on constituents in Appendix VIII.	F Series
261.32	Hazardous waste from specific sources		K Series
261.33(e)	Acute hazardous wastes (discarded commercial chemical products)	These chemical products are hazardous wastes if they are discarded. Subject to small quantity exclusion. (261.5(c))	P Series Generic names and those trade names which the Agency was aware
261.33(f)	Toxic wastes (discarded commercial chemical products)	These chemical products are hazardous wastes if they are discarded.	U Series Generic names and those trade names of which the Agency was aware
Appendix VII	Basis for Listing Hazardous Wastes	Hazardous constituents which are found in waste streams listed in 261.31 and 261.32.	F & K Series Generic names
Appendix VIII	Hazardous constituents	Hazardous constituents that are or will be subject to regulation. Specific wastes drawn from Appendix VIII are listed under 261.31, 261.32, 261.33(e), or 261.33(f).	Not numbered Generic names
	Characteristics	Wastes with any of these specified characteristics are hazardous.	If not elsewhere listed:
261.21	Ignitability		D001
261.22	Corrosivity		D002
261.23	Reactivity		D003
261.24	EP Toxicity	Waste containing any of the 14 contaminants at equal or greater concentrations than listed are hazardous wastes.	D004-D017

is regulated as a "toxic" (hazardous) waste (listed under 261.33(f) with the Hazardous Waste Number U009). Particular wastes containing acrylonitrile are also specifically listed in Section 261.32, for example:

Hazardous Waste No.	Hazardous Waste
K011	Bottom stream from the waste water stripper in the production of acrylonitrile
K013	Bottom stream from the acetonitrile column in the production of acrylonitrile.

To find out what hazardous constituents are associated with these waste streams, we turn to Appendix VII, which shows:

Hazardous Waste No.	Basis for Listing
K011	acrylonitrile, acetonitrile, hydrocyanic acid
K013	hydrocyanic acid, acrylonitrile, acetonitrile

Thus, there are two ways in which acrylonitrile falls under Subtitle C regulations: as a discarded pure chemical, and a constituent of specific waste streams.

Naming: EPA has used CAS-preferred[14] and/or generic names for most of its lists of chemicals; in addition, some trade names of which the Agency is aware are provided. Each listed hazardous waste is assigned a Hazardous Waste Number (see Exhibit 4), which must be used by industry in complying with the notification requirements of Section 3010 of the Act and certain recordkeeping and reporting requirements (under Parts 262 through 265 and Part 122).

Test Methods: Because of the need to have generators test their own wastes to determine if they are hazardous, EPA's final rules are very explicit about test methods that can be used. For each of the four characteristics of hazardous waste, EPA provided specific standards that define the characteristic, and test methods, where applicable. (See Appendix to this paper.) EPA also outlined sampling techniques and appropriate analytic procedures for the organic and inorganic chemicals in Appendix VII that should be used in determining whether the waste in question contains a given toxic constituent.[15]

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[14] CAS-preferred names are those used by the Chemical Abstract Service of the American Chemical Society.

[15] Appendix III to the Final Rules.

Concentration and Quantities: EPA added Section 261.3 (Definition of Hazardous Waste) to its final rules to clarify questions about the proposed rules, including the issue of waste mixtures. EPA notes in its preamble that this is a very real issue "in real-world waste management, since many hazardous wastes are mixed with non-hazardous wastes or other hazardous wastes during storage, treatment, or disposal."[16] The rules state that a "mixture of solid waste and one or more listed hazardous wastes" or a waste mixture that exhibits any of the characteristics of hazardous waste is considered to be a hazardous waste.[17] EPA recognized that this approach might be unsatisfactory in some cases, because some waste mixtures commingle wastes in a way that neutralizes them, or contain only very small amounts of listed wastes, although on the other hand, some hazardous wastes will escape detection and regulation merely by being mixed with other wastes. The Agency provided for exemptions for individual facilities if they can show that their waste mixtures are not hazardous, but citing its own lack of resources, EPA noted that this rulemaking procedure would only be practical for facilities that routinely mix wastes in relatively constant proportions.

In a similar vein, EPA set an initial general exclusion limit for generators of less than 1000 kilograms per month (kg/mo) of hazardous waste (with lower limits for acutely hazardous wastes). The Agency considered three exclusion levels: 100 kg/mo, 1000 kg/mo, and 5000 kg/mo.[18] The level chosen (1000 kg/mo) would exclude 91.2 percent of the estimated 760,000 generators from regulation. However, EPA determined that its administrative resources would not be sufficient to effectively regulate hazardous waste below that level. EPA plans to initiate rulemaking within two to five years to expand Subtitle C coverage down to generators of 100 kg/mo.

At present, however, the coverage policy means that a generator of over 1000 kg/mo of wastes that contain a small quantity of listed hazardous constituents must comply with Subtitle C regulations, while a generator discarding up to 1000 kg/mo of pure toxic chemicals such as benzene, dimethylnitrosamine, or mercury is not subject to Subtitle C requirements.

Delisting: EPA revised and simplified its proposed procedures for "delisting" a waste declared hazardous. These are contained in Sections 260.20 and 260.22 of the final rules. A person petitioning the Administrator to exclude a waste at a particular generating facility from the lists in 40 CFR 261 must demonstrate that the waste does not meet any of the criteria under which it was listed as hazardous.

Exclusions: A variety of wastes have been excluded from EPA's final rules of May 19, 1980. These are summarized in Exhibit 5-5, along with the reason for excluding them.

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[16] Preamble to the Final Rules, p. 33095.

[17] 40 CFR 261.3(b)(2) and (3).

[18] Preamble to the Final Rules, pp. 33104-5.

EXHIBIT 5-5

EXCLUSIONS

Section	Exclusions	Basis for Exclusion
261.4(a)	Materials which are not solid wastes:	
	• Domestic sewage • Domestic sewage mixing with sanitary wastes passing through a sewer system to a POTW for treatment	Section 1004(27) of RCRA.
	• Industrial point source discharges regulated under the Clean Water Act, as amended, Section 402 • Irrigation return flows	Avoid duplication with CWA (Section 1004(27) of RCRA).
	• Source, special nuclear or by-product material defined by the Atomic Energy Act • In-site mining wastes	Definition of solid waste in Section 1004(27) of RCRA
261.4(b)	Solid wastes which are not hazardous wastes: • Household wastes • Agricultural or animal wastes	Legislative history of RCRA
	• Mining wastes • Fly ash waste, bottom ash waste, slag waste and flue gas emission control waste generated primarily from the combustion of coal or other fossil fuels • Drilling fluids, produced water, and other wastes associated with the exploration, development or production of crude oil, natural gas, or geothermal energy.	1980 RCRA Amendments (Section 3001(b)(2),(3))

EXHIBIT 5-5

EXCLUSIONS
(continued)

Section	Exclusions	Basis for Exclusion
261.5	Less than 1000 kilograms of hazardous wastes in a calendar month	Lack of administrative resources to regulate effectively
	Less than specified amounts of acutely hazardous chemical products (1 kilogram for chemicals in 261.33(e); containers larger than 20 liters capacity; 10 kilograms of inner liners of containers; 100 kilograms for residue or contaminated soil, water or other debris from cleanup of a spill of chemicals listed in 261.33(e).)	
261.5	Wastes which contain trivalent chromium exclusively, such as tannery wastes.	Temporary exclusion to maintain consistency of rules until EP toxicity characteristics can be amended to distinguish between trivalent and hexavalent chromium.

APPENDIX A

MEASUREMENT OF CHARACTERISTICS AND TEST METHODS

This appendix presents the definitions and measurement techniques of the four characteristics of hazardous waste. Where test methods are specified, EPA also permits equivalent test methods to be used if they are approved by EPA under the procedures set forth in 40 CFR 260.20 and 260.21. Volume I of this report includes a comparative analysis of test methods for identifying hazards.

A. IGNITABILITY (40 CFR 261.21). A solid waste exhibits the characteristic of ignitability if a representative sample of the waste has any of the following properties:

(1) It is a liquid, other than an aqueous solution containing less than 24 percent alcohol by volume, and has a flash point less than 60°C (140°F), as determined by a Pensky-Martens Closed Cup Tester, using the test method specified in ASTM Standard D-93-79, or a Setaflash Closed Cup Tester, using the test method specified in ASTM standard D-3278-78.

(2) It is not a liquid and is capable, under standard temperature and pressure, of causing fire through friction, absorption of moisture or spontaneous chemical changes and, when ignited, burns so vigorously and persistently that it creates a hazard.

(3) It is an ignitable compressed gas as defined in 49 CFR 173.300 and as determined by the test methods described in that regulation.

(4) It is an oxidizer as defined in 49 CFR 173.151.

B. CORROSIVITY (40 CFR 261.22) A solid waste exhibits the characteristic of corrosivity if a representative sample of the waste has either of the following properties:

(1) It is aqueous and has a pH less than or equal to two or greater than or equal to 12.5, as determined by a pH meter using the test method specified in the "Test Methods for the Evaluation of Solid Waste, Physical/Chemical Methods" (also described in "Methods for Analysis of Water and Wastes" EPA 600/4-79-020, March 1979).

(2) It is a liquid and corrodes steel (SAE 1020) at a rate greater than 6.35 mm (0.250 inch) per year at a test temperature of 55°C (130°F) as determined by the test method specified in NACE (National Association of Corrosion Engineers) Standard TM-01-69 as standardized in "Test Methods for the Evaluation of Solid Waste, Physical/Chemical Methods".

C. REACTIVITY (40 CFR 261.23) A solid waste exhibits the characteristic of reactivity if a representative sample of the waste has any of the following properties:

(1) It is normally unstable and readily undergoes violent change without detonating.

(2) It reacts violently with water.

(3) It forms potentially explosive mixtures with water.

(4) When mixed with water, it generates toxic gases, vapors or fumes in a quantity sufficient to present a danger to human health or the environment.

(5) It is a cyanide or sulfide bearing waste which, when exposed to pH conditions between two and 12.5, can generate toxic gases, vapors or fumes in a quantity sufficient to present a danger to human health or the environment.

(6) It is capable of detonation or explosive reaction if it is subjected to a strong initiating source or if heated under confinement.

(7) It is readily capable of detonation or explosive decomposition or reaction at standard temperature and pressure.

(8) It is a forbidden explosive as defined in 49 CFR 173.51, or a Class A explosive as defined in 49 CFR 173.53 or a Class B explosive as defined in 49 CFR 173.88.

D. EP TOXICITY (40 CFR 261.24, Appendix II) A solid waste exhibits the characteristic of EP toxicity if, using the test methods described in Appendix II of RCRA regulations or equivalent methods approved by the Administrator under the procedures set forth in §§260.20 and 260.21, the extract from a representative sample of the waste contains any of the contaminants listed in [Exhibit 2 above] at a concentration equal to or greater than the respective value given in that [Exhibit]. Where the waste contains less than 0.5 percent filterable solids, the waste itself, after filtering, is considered to be the extract.

Appendix II [of the regulations] provides (a) the extraction procedure to be followed for extracting solid components of the waste sample; (b) a separation procedure for separating the free liquid portion of the waste from any solid matter having a particle size greater than 0.45 micrometers; and (c) analytical procedures for analyzing the extract contaminants.

EPA also recommended protocols for obtaining representative samples (Appendix I) of the regulations when testing a waste sample for any of the four characteristics.

FEDERAL INSECTICIDE, FUNGICIDE AND RODENTICIDE ACT (FIFRA) -- STATUTORY REVIEW

INTRODUCTION

This statutory review is divided into three main parts. The first of these is entitled "Background" and gives a brief history of the evolution of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The second part deals with the statutory provisions of FIFRA, particularly the major actions available to EPA and the bases for these actions. The final part investigates some of the standards which the courts have established for cases arising under FIFRA. Particular attention is paid there to why the courts often avoid reaching substantive issues in these cases and to the standards which have evolved for review of suspension and cancellation orders.

BACKGROUND

The purpose of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)[1] is to regulate the use of pesticides in order to prevent "unreasonable adverse effects" on the environment. The environment includes "water, air, land and all plants and man and other animals living therein, and the interrelationships which exist among these."[2]

The pesticide program was originally located in the Department of Agriculture. Since 1970, FIFRA has been administered by the Environmental Protection Agency (EPA). The Act assigns responsibility to EPA in three major areas.[3] First, the Agency administers a registration program under which no "pesticide" can be shipped, delivered, or sold within the United States without first being registered with EPA. This process is intended to enable EPA to judge a product's safety before allowing it to be marketed. EPA is required by statute to publish the guidelines which govern the registration process. Second, EPA administers a program under which registered pesticides are classified as being available for either general use or restricted use. This classification results in restrictions on the methods by which or amounts in which certain pesticides can be applied or used. Third, EPA can cancel or suspend the use of any previously registered pesticide which the Agency has determined to be unreasonably unsafe.

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[1] 7 USC §§136 *et seq*.

[2] Section 2(j). Unless otherwise specified, statutory references will be to FIFRA.

[3] EPA is also charged with other duties such as monitoring the disposal of unused pesticides and providing the Secretary of Transportaion with assistance in fulfilling his responsibilities for the transportation of hazardous materials.

The first legislation concerned with the use of chemical pesticides was the Federal Insecticide Act of 1910. This legislation was replaced by FIFRA in 1947, which authorized the registration of pesticides used in intrastate and interstate commerce. The authority to deny or suspend registration, which effectively prohibits the use of some pesticides, was not granted until 1964. The emphasis, however, was still on protection of consumers from ineffective products.

A significant change occured when FIFRA was substantially amended by the Federal Environmental Pesticide Control Act of 1972. These amendments reflected the growing concern about the potential adverse effects of pesticides and changed FIFRA from a labeling law to a regulatory statute. The Administrator of EPA is now required to register all pesticides before they can be shipped, delivered or sold within the United States, including intrastate as well as interstate commerce.[4] The process of registration requires the review of premarket data for new products against the risks to the environment posed by their use. In addition, EPA reexamines previously registered products, reregistering only those which meet current safety standards. The registration of those products which have "unreasonable adverse effects" on the environment is denied or cancelled.

In 1975, amendments to FIFRA specified that the Agency must submit its proposed cancellation of registration actions to a Scientific Advisory Panel and to the Secretary of Agriculture before initiating cancellation proceedings.[5] The Agency must specifically analyse the impact of its decision on the production of agricultural commodities, retail food prices, and other aspects of the agricultural economy.[6] This essentially reinforces the Agency's mandate to weigh the benefits of pesticide use against the risks to the environment.

FIFRA was again amended in 1978. Many of the 1978 amendments to FIFRA reflect the difficulties EPA encountered in reregistering thousands of pesticide products. The amendments:

- authorize a simplified approach to registration (Section 3(c)(2)(C)) which is the basis for the Agency's proposed generic Registration Standards Program under which it will adopt a chemical-by-chemical approach to registration rather than a product-by-product approach as was previously required (44 Federal Register 76311, December 26, 1979);

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[4] The states themselves may also legislate to control pesticides; such legislation must provide safeguards at least as demanding as those of FIFRA.

[5] Sections 6(b)and 25(d).

[6] Organized Migrants in Community Action v. Brennan, 520 F.2d 1161 (D.C. Cir. 1975) held that, pursuant to FIFRA, EPA, not the Secretary of Labor under the Occupational Safety and Health Act, has authority to provide protection for farmworkers from hazards arising from pesticide exposure.

- authorize conditional registration of pesticides (such as those whose formulations are similar to already registered pesticides) to allow greater flexibility in fulfilling data requirements (Section 3(c)(7));
- authorize waiver of the finding of efficacy as a requirement for registration in order to concentrate the Agency's resources on assessment of health and safety questions (Section 3(c)(5));
- direct EPA to consider restriction of pesticide use as an alternative to total cancellation;
- direct EPA to prepare an agricultural impact statement for any regulations issued; and
- authorize EPA to classify registered pesticides for restricted use by regulation prior to full re-registration.

In addition, Section 3(c)(8) explicitly states that the Administrator may not undertake a risk-benefit analysis of a pesticide prior to initiating formal proceedings to cancel, suspend, or deny registration unless the action is based on a validated test or other significant evidence concerning unreasonable risk to man or the environment.

STATUTORY PROVISIONS

The key provisions of FIFRA for purposes of this statutory review include the following:

- Section 2 Definitions of Substances Subject to Regulation
- Statutory Criteria for Registration (Sections 3(a)-(c), Classification (§3(d)), Cancellation of Registration (§§6(a)-(b)), and Suspension ((§6(c))
- Other Regulatory Authority (§§19, 25)

These provisions will be reviewed next.

Chemical Substances Subject to Regulation

FIFRA allows regulation of any chemical which qualifies as a "pesticide." Pesticide is defined as "(1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, and (2) any substance or mixture of substances intended for use as a

EXHIBIT 6-1

OVERVIEW OF STATUTORY CRITERIA

ACTION	CRITERIA
Deny registration or re-registration for some or all uses of a pesticide	(1) The pesticide's composition does not warrant the proposed claim for it; (2) Its labeling does not comply with FIFRA requirements; (3) It will not perform its intended function without unreasonable adverse effects on the environment; Section 3(c)(5)(C) or (4) When used in accordance with widespread and commonly recognized practice, it will generally cause unreasonable adverse effects on the environment. (Section 3(c)(6))
Cancellation of registration	(1) If pesticide or its labeling does not comply with FIFRA provisions (2) When used in accordance with widespread and commonly recognized practice, it will generally cause unreasonable adverse effects on the environment. (3) EPA must consider restricting a pesticide's use(s) as an alternative to cancellation; and shall take into account the impact of cancellation on production and prices of agricultural commodities, retail food prices, and the agricultural economy. (Section 6(b))
Conditional registration	Action would not significantly increase the risk of any unreasonable adverse effect on the environment. (Section 3(c)(7))

EXHIBIT 6-1

OVERVIEW OF STATUTORY CRITERIA
(Continued)

ACTION	CRITERIA
Restricted use classification	The pesticide, when applied in accordance wih its directions for use or in accordance with a widespread and commonly recognized practice, may generally cause, without additional regulatory restrictions, unreasonable adverse effects on the environment, including injury to the applicator. (Section 3(d)(1)(C))
Change in use classification	Change to restricted use classification is necessary to prevent unreasonable adverse effects on the environment. (Section 3(d)(2))
	Change to general use would not cause unreasonable adverse effects on the environment. (Section 3(d)(3))
Suspension of registration	Registration may be suspended immediately after an opportunity for a hearing if necessary to prevent an imminent hazard during the time required for cancellation or change in classification proceedings (Section 6(c)(1)). If an emergency exists that does not permit a hearing before suspension, EPA may suspend registration immediately, pending issuance of a final order following a hearing (Section 6(c)(3)).

plant regulator, defoliant, or desiccant. . . ."[7] The focus of the definition is on the intended use of the product. Thus the definition allows the regulation of as broad a range of chemicals as might be used to combat pests or to regulate plant growth.[8]

FIFRA recognizes two distinct groups of substances which comprise a pesticide: (1) active ingredients and (2) inert ingredients. The former produce the pesticide's effects, the latter do not.[9] FIFRA requires pesticides containing arsenic in any form to include in their ingredient statement the percentage of both total and water soluble arsenic, calculated as elementary arsenic.[10] The statute does not otherwise single out any chemical substances for special treatment when included in pesticides.

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[7] Section 2(u). See 40 CFR 162.4(a), "Determination of intent of use," which states: "A substance or mixture of substances is a pesticide under the Act if it is intended for preventing, destroying, repelling, or mitigating any pest. . . . Such intent may be either expressed or implied. If a product is represented in any manner that results in its being used as a pesticide it shall be deemed to be a pesticide for the purposes of the Act and these regulations."

[8] The term "pest" means "(1) any insect, rodent, nematode, fungus, weed, or (2) any other form of terrestrial or aquatic plant or animal life or virus, bacteria, or other micro-organisms (except viruses, bacteria, or other micro-organisms on or in living man or other living animals) which the Administrator declares to be a pest under section 25(c)(1)." Section 2(t). Despite the broad definition of a pesticide, FIFRA identifies certain exceptions including (1) "new animal drugs" within the meaning of Section 201(w) of the Federal Food, Drug, and Cosmetic Act (21 USC §321(w)); (2) articles determined not to be new animal drugs by a regulation establishing conditions for its use; or (3) animal feed bearing or containing an article covered by (1) and (2) (21 USC §321(x)). The term "plant regulator" means "any substance or mixture of substances intended, through physiological action, for accelerating or retarding the rate of growth or rate of maturation, or for otherwise altering the behavior of plants or the produce thereof, but shall not include substances to the extent that they are intended as plant nutrients, trace elements, nutritional chemicals, plant inoculants, and soil amendments. Also, the term 'plant regulator' shall not be required to include any of such of those nutrient mixtures or soil amendments as are commonly known as vitamin-hormone horticultural products, intended for improvement, maintenance, survival, health, and propagation of plants, and as such are not for pest destruction and are nontoxic, nonpoisonous in the undiluted packaged concentration." Section 2(v).

[9] Section 2(a), 2(m).

[10] Section 2(n)(2).

Section 2 also defines the key criterion of FIFRA, "unreasonable adverse effects on the environment", as follows: "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide."[11] The phrase "unreasonable risk" is not further defined.

To "protect health and the environment" under FIFRA means to protect "against any unreasonable adverse effects on the environment" where the environment includes "water, air, land, and all plants and man and other animals living therein, and the interrelationships which exist among these."[12]

Section 2(l) defines "imminent hazard" as a situation arising from the continued use of a pesticide which results in (1) "unreasonable adverse effects on the environment", or (2) "the unreasonable hazard to the survival of a species declared endangered by the Secretary of the Interior under Public Law 91-135."

Criteria for Regulatory Action

In this section, we discuss the criteria for the four major actions which are available to EPA under FIFRA: Registration (or denial of it), cancellation, suspension, and restrictions on use (called "classification" in FIFRA).

Applications for registration are to be judged according to statutory direction (and regulations set forth at 40 CFR 162). Generally, EPA should approve registration if a given pesticide "will perform its intended function without unreasonable adverse effects on the environment."[13] The criterion "unreasonable adverse effects on the environment" means "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide."[14] The EPA Administrator at his discretion can require further testing of a pesticide or can issue an experimental use permit before making a decision on an application for registration. The burden of proof and persuasion is on the applicant.

If a pesticide is determined, after its initial registration, to cause "unreasonable adverse effects on the environment," the Administrator can cancel it.[15] Cancellation requires notice to the persons affected and an opportunity for a hearing to consider the need for the action. In extreme cases, the Administrator can suspend a pesticide's permit pending cancellation proceedings. There are two kinds of suspensions available to EPA, ordinary suspension and emergency suspension. Grounds for ordinary suspension exist when further use of the pesticide would create an "imminent hazard".[16] Ordinary suspension requires that notice be sent to the registrant and a hearing be held if requested.[17] An emergency suspension does not require prior notice or hearing, but may only be ordered when EPA determines that an emergency exists.[18] The term "emergency" is not defined in FIFRA.

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[11] Section 2(bb).

[12] Sections 2(x), 2(j).

[13] Section 3(c)(5)(C).

[14] Section (2)(bb)

[15] Section 6(b).

EPA has another option for controlling the risks associated with pesticide use. It can classify the pesticide for "restricted use" (i.e., application only by a certified applicator) if necessary to prevent "unreasonable adverse effects."[19]

Other Regulatory Authority

Sections 19 and 25 of FIFRA provide further regulatory authority over certain pesticide chemicals. Section 19 addresses issues of pesticide disposal and transport. The emphasis is on the proper disposal of pesticides whose registrations have been suspended. Section 25 contains general authority to register and exempt chemicals and also, in subsection (C)(3), specific authority to establish packaging standards for pesticides.

Regulations issued under Section 25 must "take into account the difference in concept and usage between various classes of pesticides and differences in environmental risk and the appropriate data for evaluating such risk between agricultural and nonagricultural pesticides."[20] The EPA Administrator has the authority to exempt from the requirements of FIFRA any pesticide which is either (1) adequately regulated by another federal agency or (2) of a character which is unnecesary to be subject to FIFRA in order to carry out its purpose to protect health and the environment.[21]

Other authority granted by Section 25(c) includes the power:

- "to determine any pesticide which contains any substance or substances in quantities highly toxic to man";

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[16] Section 6(c)(1).

[17] Section 6(c).

[18] Section 6(c)(3).

[19] Section 3(d)(1).

[20] Section 25(a)(1).

[21] Section 25(b).

- to require pesticides to be colored or discolored if "such requirement is feasible and is necessary for the protection of health and the environment;"
- to determine and establish suitable names to be used in the ingredient statement; and
- to establish standards with respect to the package, container, or wrapping of a pesticide "in order to protect children and adults from serious injury or illness resulting from accidental ingestion or contact".

Packaging standards for pesticides must be consistent with those established under the authority of the Poison Prevention Packaging Act (P.L. 91-601).[22]

JUDICIAL INTERPRETATIONS

Summary

In ruling on controversies arising under FIFRA, few courts have set out constructive, substantive standards for EPA to follow in administering FIFRA and none of these courts has established any comprehensive set of standards for EPA. There are a number of reasons why this is so, including the deference given to EPA on technical matters, the standard of judicial review utilized, and the burden of proof employed in these cases. These factors, and how they cause this lack of substantive standards, is explained first.

Following that section, we review the case law which does exist pertaining to the particular actions which EPA can take with respect to registration. We investigate in particular detail the judicial guidance which has been given on suspension. For ordinary suspensions, the courts have ruled on the nature of the suspension order (a "preliminary assessment" rather than an ultimate resolution of the situation, such as cancellation); the basis required for suspension; the cost-benefit analysis which must be undertaken; and the standards applicable to the definition of "imminent hazard". On the subject of emergency suspensions, the major case in the area has defined the term "emergency" and established five factors to be examined in testing for the existence of an "emergency". The last action discussed is cancellation of registration--the topics considered here are: the standards necessary for registration in general, the delicate balancing test to be employed in cancellation actions, and the differences between the standards used in reviewing cancellation and suspension orders. We have not included separate sections for actions involving denial of registration or limitation on the use of previously registered products, because few cases provide substantive guidance in these areas.

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[22] Section 25(c)(3). See discussion in Volume 3.

The Roles of the Courts and EPA

The courts have repeatedly said that they will give great deference to EPA in its decisions, especially on technical matters. As stated in Environmental Defense Fund, Inc.[23] v. Blum[24] (dealing with an EPA order allowing limited use of Mirex to help control fire ants):

> The Court's review in this respect is highly deferential and presumes the agency's action to be valid. Particularly is this true in cases where the agency's decision rests predominantly on technical and scientific data in an area where much discretion has been delegated to it by Congress. [Citations omitted.]

EPA has been given discretion to set policy, not only find facts, and this discretion is particularly broad in cases involving interim relief:

> We begin with the proposition that, within broad limits, the administrator has latitude not merely to find facts, but also to set policy in the public interest. Like most regulatory statutes, the FIFRA confers broad discretion on the Secretary. It is particularly appropriate to defer to that discretion when the question at issue is a matter of interim relief, as it is in this case.[25]

One judge in the U.S. District Court for the Eastern District of Michigan, in Dow Chemical Company v. Blum,[26] went so far as to deny a stay of EPA's order for an emergency suspension even though that court would not itself have ordered the suspension.

This deference does not mean that courts will blindly uphold EPA's decisions. The courts require, among other things, that EPA give adequate reasoning for its rulings. In EDF v. EPA,[27] dealing with EPA's failure to suspend registrations of aldrin and dieldrin, Judge Leventhal of the District of Columbia Court of Appeals stated:

> Our comments according EPA substantial policy choice and discretion are not to be taken as mere lip service to established principle, that is

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[23] Henceforth, the Environmental Defense Fund, Inc. shall be referred to as "EDF".

[24] 458 F.Supp. 650,651 (DC D.C. 1978).

[25] Wellford v. Ruckelshaus, 439 F.2d 598,601 (D.C. Cir. 1971) (EPA refusal to suspend 2,4,5-T). See also, EDF v. Ruckelshaus, 439 F.2d 584,596 (D.C. Cir. 1971) dealing with refusal to suspend DDT registration (". . . we have recognized that it is particularly appropriate to defer to administrative findings of fact in reviewing a decision on a question of interim relief.") [Footnote omitted.].

[26] 458 F.Supp. 650 (E.D. Mich. 1979).

[27] 465 F.2d 528,540-541 (D.C. Cir. 1972).

> undercut by the need we find for better articulation. . . . Our own responsibility as a court is as a partner in the overall administrative process--acting with restraint, but providing supervision. We cannot discharge our role adequately unless we hold EPA to a high standard of articulation. [Footnote omitted.]

In EDF v. Ruckelshaus,[28] while considering EPA's refusal to suspend DDT, the court gave this excellent summary of the relationship of the courts and EPA, but came to the same conclusion:

> We stand on the threshold of a new era in the history of the long and fruitful collaboration of administrative agencies and reviewing courts. For many years, courts have treated administrative policy decisions with great deference, confining judicial attention primarily to matters of procedure. On matters of substance, the courts regularly upheld agency action, with a nod in the direction of the 'substantial evidence' test, and a bow to the mysteries of administrative expertise. Courts occasionally asserted, but less often exercised, the power to set aside agency action on the ground that an impermissible factor had entered into the decision, or a crucial factor had not been considered. Gradually, however, that power has come into more frequent use, and with it, the requirement that administrators articulate the factors on which they base their decisions.
>
> Strict adherence to that requirement is especially important now . . . [C]ourts are increasingly asked to review administrative action that touches on fundamental personal interests in life, health, and liberty. These interests have always had a special claim to judicial protection, in comparison with the economic interests at stake in a ratemaking or licensing proceeding.
>
> To protect these interests from administrative arbitrariness, it is necessary, but not sufficient, to insist on strict judicial scrutiny of administrative action. For judicial review alone can correct only the most egregious abuses. Judicial review must operate to ensure that the administrative process itself will confine and control the exercise of discretion. Courts should require administrative officers to articulate the standards and principles that govern their discretionary decisions in as much detail as possible.
>
> Rules and regulations should be freely formulated by administrators, and revised when necessary. Discretionary

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[28] 439 F.2d 584, 597-598 (D.C. Cir. 1971).

> decisions should more often be supported with findings of fact and reasoned opinions. When administrators provide a framework for principled decision-making, the result will be to diminish the importance of judicial review by enhancing the integrity of the administrative process, and to improve the quality of judicial review in those cases where judicial review is sought. [Footnotes omitted.]

The fact remains, however, that the courts have given great deference to decisions of the EPA. As a result, the case law presents few rulings on substantive issues.

A second major reason for the existence of little substantive guidance from the courts is the standard used in deciding cases that review EPA orders made after public hearing. This standard is set out in Section 16(b) of FIFRA: "The order of the Administrator shall be sustained if it is supported by substantial evidence when considered on the record as a whole." As stated in EDF v. EPA,[29] dealing wih the suspension of aldrin and dieldrin:

> The standard of 'substantial evidence' means
>
>> something less than the weight of the evidence . . . [T]he possibility of drawing two inconsistent conclusions from the evidence does not prevent an administrative agency's finding from being supported by substantial evidence. [Footnote omitted.]

See also EDF v. EPA,[30] reviewing the suspension of heptachlor and chlordane. Application of this standard means that the court must investigate the substantive issues only far enough to satisfy itself that there is respectable authority for the Administrator's ruling. Thus, rarely will the court be setting its own standards; it will usually only look at the reasonableness of those established by EPA.

The third reason why courts often do not reach substantive issues in cases under FIFRA is the burden of proof applicable to such cases. "The burden of establishing the safety of a product requisite for compliance with the labeling requirements, remains at all times on the applicant and registrant." EDF v. EPA[31] (aldrin and dieldrin); EDF v. EPA[32] (aldrin and dieldrin); EDF v. EPA[33] (heptachlor and chlordane). See also

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[29] 510 F.2d 1292, 1298 (D.C. Cir. 1975).

[30] 548 F.2d 998, 1003 (D.C. Cir. 1976), cert. denied 431 U.S. 925 (1977).

[31] 465 F.2d 528, 532 (D.C. Cir. 1972).

[32] 510 F.2d 1292, 1297 (D.C. Cir. 1975).

[33] 548 F.2d 988, 1004 (D.C. Cir. 1976), cert. denied 431 U.S. 925 (1977).

Dow Chemical Company v. Blum[34] (emergency suspension of 2,4,5-T and Silvex). When a court holds that the applicant or registrant has not met this burden, it does not need to look into the merits of the action, and again a substantive decision is often avoided.

The purpose of this section has not been to describe the procedural vagaries of our court system but rather to give a flavor for the many reasons why judges often avoid substantive issues in cases dealing with FIFRA. In the sections which follow, we review some of the standards that the courts have established. Bear in mind, however, that most of the standards and criteria for FIFRA are established by legislative and administrative action, not by the courts.

The Standards Established for Different Actions by EPA

The actions of EPA relevant to this review are: denial of registration, suspension of registration, cancellation of registration, and restriction on use. Most of the cases setting substantive standards have dealt only with suspension or cancellation. Many of the principles established with respect to these actions are relevant to others, and so our discussion will center around those actions for which judicial standards have been established.

Suspension

There are two suspension of registration actions available to EPA -- ordinary suspension and emergency suspension (suspension prior to either a hearing or notification of the registrant). The first case concerning an emergency suspension by EPA under FIFRA Section 6(c)(3) was decided only last year. Much more law, therefore, exists with respect to ordinary suspensions, which will be discussed first.

Ordinary Suspensions. It has been held by several courts that:

> Although cancellation notices should issue as soon as the Secretary finds a substantial question concerning the safety of a registered product, he reserves the suspension power for cases in which serious and irreparable harm to the public health is likely to occur before the conclusion of the ordinary cancellation process. Wellford v. Ruckelshaus[35] (Dealing with EPA refusal to suspend 2,4,5-T).

Thus, the suspension power plays a crucial role in the set of options available to EPA. In EDF v. Ruckelshaus (DDT)[36] the court said:

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[34] 469 F. Supp. 892, 906 (E.D. Mich. 1979).

[35] 439 F.2d 598, 601-602 (D.C. Cir. 1971), quoted in Dow Chemical Company v. Ruckelshaus, 477 F.2d 1317,1319 (8th Cir. 1973) (also dealing with 2,4,5-T).

[36] 439 F.2d 584, 596 (D.C. Cir. 1971).

> The formulation of standards for suspension is entrusted to the Secretary in the first instance, but the court has an obligation to ensure that the administrative standards conform to the legislative purpose, and that they are uniformly applied in individual cases.

In establishing such standards, the courts have noted that the purpose of a suspension decision is not to make an "ultimate resolution of difficult issues," but instead to make a "preliminary assessment of the evidence." EDF v. EPA,[37] (failure to suspend aldrin and dieldrin); EDF v. EPA[38] (suspension of aldrin and dieldrin); EDF v. EPA[39] (heptachlor and chlordane).

In this last case cited, Judge Leventhal, speaking for the District of Columbia Court of Appeals, stated:

> We note, however, that we come to this conclusion in the context of a suspension proceeding where perforce the Administrator is engaged in making a 'preliminary assessment' of the evidence; a more careful exploration of economic impact and available alternatives would be required to support continued registration in a cancellation proceeding.

A distinction has been made, therefore, between the level of analysis needed to support a cancellation order (a "careful exploration") and for a suspension proceeding (a "preliminary assessment").

What kind of basis is necessary for this "preliminary assessment"? We have already discussed (in the section, "The Roles of the Courts and EPA") the "substantial evidence" standard which the courts use as their basis for reviewing EPA decisions. This is to be distinguished from the evidentiary basis which EPA must require in proceedings before it, which is the subject of this discussion. The District of Columbia Court of Appeals held, in EDF v. EPA[40] (suspension of aldrin and dieldrin), that since general data such as laboratory experiments on animals has been found to be sufficient to support a cancellation order, the same principle should apply to a suspension proceeding where only a "preliminary assessment" is made.[41] The court in EDF v. EPA,[42] (suspension of aldrin and dieldrin affirmed) also stated that:

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[37] 465 F.2d 528, 537 (D.C. Cir. 1972)

[38] 510 F.2d 1292, 1298 (D.C. Cir. 1975)

[39] 548 F.2d 998, 1004 (D.C. Cir. 1976), cert. denied 431 U.S. 925 (1977).

[40] 510 F.2d 1292, 1301-1302 (D.C. Cir. 1975)

> When cancer is involved, it has been stated that "even a court scrupulous to the point of punctilious in deference to administrative latitude is beset with concern" when EPA makes only a short reference to carcinogenicity in denying suspension of substances for which a "non-trivial" link to cancer has been shown. EDF v. EPA,[43] (failure to suspend aldrin and dieldrin remanded to EPA for reconsideration).

Thus, where cancer is in issue, greater support for an EPA action which potentially endangers public health may be required.

We have seen that general data may form a sufficient basis for an EPA determination of suspension, but we have yet to deal with the cost-benefit analysis which lies at the heart of such a determination. In EDF v. EPA[44] (heptachlor and chlordane), the court stated:

> To evaluate whether use of a pesticide poses an 'unreasonable risk to man or the environment,' the Administrator engages in a cost-benefit analysis that takes 'into account the economic, social, and environmental costs and benefits of the use of any pesticide.' 7 USC §136(bb).

Further elucidation of this point was given in Wellford v. Ruckelshaus[45] (2,4,5-T),

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[41] See also EDF v. EPA, 548 F.2d 998, 1005 (D.C. Cir. 1976), cert. denied 431 U.S. 925 (1977) (heptachlor and chlordane).

[42] 510 F.2d 1292, 1298 (D.C. Cir. 1975)

> '[W]here the matter involved is as sensitive and fright-laden as cancer,' and the statute places the burden on the registrant to establish the safety of his product, we shall not, assuming a substantial showing of danger, require the Administrator to make impossible proofs. In reviewing administrative actions, courts 'cannot fairly demand the perfect at the expense of the achievable.' [Footnotes omitted.]

[43] 465 F.2d 528, 537-538 (D.C. Cir. 1972).

[44] 548 F.2d 998, 1005 (D.C. Cir. 1976), cert. denied 431 U.S. 925 (1977).

[45] 439 F.2d 598, 602 (D.C. Cir. 1971).

> In order to apply his standard to a particular product, the Secretary must first determine what harm, if any, is likely to flow from the use of the product during the course of administrative proceedings. He must consider both the magnitude of the anticipated harm, and the likelihood that it will occur. Then, on the basis of that factual determination, he must decide whether the anticipated harm amounts to an 'imminent hazard to the public.'

As stated in *EDF v. Ruckelshaus* (DDT),[46] there is

> a heavy burden on any administrative officer to explain the basis for his decision to permit the continued use of a chemical known to produce cancer in experimental animals. [Footnote omitted.]

The suspension power, therefore, is designed to prevent serious and irreparable harm to public health during the cancellation litigation.[47] In *EDF v. EPA*,[48] the court held:

> Judicial doctrine teaches that a court must consider possibility of success on the merits, the nature and extent of the damage to each of the parties from the granting or denial of the injunction, and where the public interest lies. It was not inappropriate for the Administrator to have chosen a general approach to suspension that permits analysis of similar factors. By definition, a substantial question of safety exists when notices of cancellation issue. If there is no offsetting claim of any benefit to the public, then the EPA has the burden of showing that the substantial safety question does not pose an 'imminent hazard' to the public. [Footnote omitted.]

In that case, EDF was questioning EPA's cost-benefit analysis which led to a failure to suspend registration of aldrin and dieldrin. The District of Columbia Court of Appeals ruled:

> The Administrator's mere mention of these products' major uses, emphasized by the EPA, cannot suffice as a discussion of benefits. . . .
>
> The interests at stake here are too important to permit the decision to be sustained on the basis of speculative

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[46] 439 F.2d 584, 596 n.41 (D.C. Cir. 1971) quoted in *EDF v. EPA*, 510 F.2d 1292, 1302 (D.C. Cir. 1975) (aldrin and dieldrin), and cited in *EDF v. EPA*, 548 F.2d 998, 1005 (D.C. Cir. 1976), *cert. denied* 431 U.S. 925 (1977) (heptachlor and chlordane).

[47] *See* *Wellford v. Ruckelshaus*, 439 F.2d 598 (D.C. Cir. 1971) (2,4,5-T); *EDF v. EPA*, 465 F.2d 528 (D.C. Cir. 1972) (aldrin and dieldrin).

[48] 465 F.2d 528, 539 (D.C. Cir. 1972).

> inference as to what the Administrator's findings and conclusions might have been regarding benefits. Sound principle sustains the practice of vesting choice of policy with the Administrator. Its corollary is that the specific decision must be explained, not merely explainable, in terms of the ingredients announced by the Administrator as comprising the Agency's policies and standards. This is the case even though the variables of the policy approach selected by the Administrator are not necessarily required by the underlying statute.
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> Our conclusion that a mere recitation of a pesticide's uses does not suffice as an analysis of benefits is fortified where . . . alternative pest control mechanisms are available for such use. The analysis of benefit requires some consideration of whether such proposed alternatives are available or feasible, or whether such availability is in doubt. [Footnote omitted.][49]

This case went on to stress the importance of an analysis of benefits (as well as harm) by EPA. The conclusion we can draw from this case is that EPA has a significant burden to overcome in refusing to suspend registration where it has been shown that public safety is threatened.

How is EPA to decide when public safety is threatened sufficiently to warrant a suspension? Section 6(c) of FIFRA provides that suspension shall be ordered if EPA "determines that action is necessary to prevent an imminent hazard during the time required for cancellation or change in classification proceedings." "Imminent hazard" is defined in Section 2(l) to be a situation which would result in "unreasonable adverse effects on the environment" or "will involve unreasonable hazard to the survival" of endangered species. "Unreasonable adverse effects on the environment" is also defined, in Section 2(bb), to be "unreasonable risk to man or the environment," weighing the costs and benefits as we have already discussed. These are fairly sterile definitions, however, and the courts have given some guidance in their application.

The leading case on the definition of "imminent hazard" is EDF v. EPA,[50] (aldrin and dieldrin) in which the court stated:

> But we must caution against any approach to the term "imminent hazard," used in the statute, that restricts it to a concept of crisis. It is enough if there is substantial likelihood that serious harm will be experienced during the year or two required in any realistic projection of the administrative process. [Emphasis added.]

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[49] 465 F.2d at 539. Note how this dovetails with the quotation from this case cited earlier (in the section "The Roles of the Court, and EPA") emphasizing the need for better articulation by EPA of the rationale for its actions.

[50] 465 F.2d 528, 540 (D.C. Cir. 1972).

See *EDF v. EPA*[51] (aldrin and dieldrin); *EDF v. EPA* (heptachlor and chlordane),[52] both of which quote from this case. This approach seems consistent with these prior conclusions concerning "imminent hazard to public health" made under earlier versions of FIFRA by the Secretary of Agriculture (then in charge of administering FIFRA) and upheld by the court in EPA v. *Ruckelshaus* (DDT)[53]:

> . . . the most important element of an 'imminent hazard to the public' is a serious threat to public health, . . . a hazard may be 'imminent' even if its impact will not be apparent for many years and . . . the 'public' protected by the suspension provision includes fish and wildlife. [Footnotes omitted.]

What we have presented here is a brief summary of the judicial guidance which has been given with respect to several of the major issues involved in ordinary suspension proceedings, namely the sufficiency of the basis required for agency decision, what is necessary for cost-benefit analyses, and what is "imminent hazard". In the next part of this section, we investigate a few of the issues raised by emergency suspensions.

Emergency Suspensions

The first case considering an emergency suspension by EPA pursuant to Section 6(c)(3) of FIFRA is *Dow Chemical Company v. Blum*[54] (2,4,5-T and Silvex). An emergency suspension order may be issued prior to a hearing and prior to notifying the registrant if the Administrator determines that an emergency exists. As stated in that case,

> The term 'emergency' is not defined in the Act, legislative history, regulations, or the cases. EPA has interpreted the term to mean a threat of harm to humans and the environment so immediate that the continuation of pesticide use is likely to result in unreasonable adverse effects during a suspension hearing. [Citation omitted.][55]

The court gave this guidance concerning its role in reviewing emergency suspensions:

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[51] 510 F.2d 1292,1297 (D.C. Cir. 1975).

[52] 548 F.2d 998,1005 (D.C. Cir. 1976), *cert. denied* 431 U.S. 925 (1977).

[53] 439 F.2d 584,597 (D.C. Cir. 1971).

[54] 469 F. Supp. 892 (E.D. Mich. 1979).

[55] 469 F. Supp. at 901.

> Thus, in examining the EPA decision in this case, the Court must keep in mind that it was the Congressional intent that potentially dangerous pesticides should be removed from the market witout delay and that EPA be given expanded authority to regulate pesticides.[58]

In commmenting on EPA's definition of the term "emergency," the court held that it was "substantially valid" but went on to say:

> Because there is no precedent for the Court to follow in this action, it is appropriate to define the term 'emergency' by referance to the principles and rationale for the granting by a court of a temporary restraining order. The purpose of a temporary restraining order is to prevent immediate and irreparable harm to the complaining party. . . during the period necessary to conduct a hearing on a preliminary injunction. The definition of the 'emergency' by the EPA reflects this same basic rationale--to prevent unreasonable adverse effects on the environment during the time necessary to conduct a suspension hearing. . . .
>
> In light of recent cases in the analogous area of review of suspension orders issued after a hearing, however, the EPA definition requires refinement. The Courts hold the standard of review in this instance is whether there is a substantial likelihood that serious harm will be experienced during the year or two required in any realistic projection of the administrative process. By analogy to this standard, the term 'emergency' should be defined as follows: whether there is a substantial likelihood that serious harm will be experienced during the three or four months required in any realistic projection of the administrative suspension process. This test, coupled with the purposes behind the hearing requirement, suggests the necessity to examine five factors:
>
> (1) The seriousness of the threatened harm;
>
> (2) The immediacy of the threatened harm;
>
> (3) The probability that the threatened harm would result;
>
> (4) Benefits to the public of the continued use of the pesticides in question during the suspension process; and

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[58] 469 F. Supp. at 900. In coming to this conclusion, the court reviewed the legislative history of FIFRA, particularly Senate Report 92-838, 1972 U.S. Code Cong. & Adm. News 3993,3996-8; Senate Report 92-970, 1972 U.S. Code Cong. & Adm. News 4094; 118 Cong. Rec. 32259-32260 (September 26, 1972).

> (5) The nature and extent of the information before the Administrator at the time he made his decision.
>
> [Citations omitted.] [Emphasis added.][57]

This is among the clearest, most complete set of substantive standards any court has articulated for action under FIFRA. The definition of emergency is based on an analogy to the imminent hazard standard which we have discussed above at length. The five-prong analysis suggested is to be performed with the purposes of the emergency provision and its costs (no prior hearing or notice) in mind. This test seems logically sound and should be specific enough to be helpful to EPA in future situations involving potential emergency situations.

Registration Cancellations

This section reviews judicial standards established for orders by EPA cancelling registration under FIFRA. We have already established that suspensions are more temporary than cancellations (see discussion under "Ordinary Suspension"). It should be pointed out here, however, that although cancellations may be more final than suspensions, they involve "less urgent considerations" because of the "imminent hazard" standard applicable to suspension proceedings. Dow Chemical Company v. Ruckelshaus (2,4,5-T).[58] The remainder of this discussion will focus on some of these considerations, namely, the standards a product must meet to be registered, the balancing test to be used in cancellation proceedings, and the type and level of proof required.

In Stearns Electric Paste Co., v. EPA,[59] a case setting aside cancellation orders of a rat poison, the court summarized the standards a product must meet in order to be registered:

> First, the product must be effective; more precisely, it must be at least as effective as the registrant claims it to be...[60]
>
> Second, the product must satisfy certain safety standards. Although the definition of the term "adulterated" in other legislation embodies safety considerations, in FIFRA it is the definition of the term "misbranded" that identifies the statutory standards of product safety.[61] [Footnote omitted.]

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[57] 469 F. Supp. at 901,902.

[58] 477 F.2d 1317, 1323 (8th Cir. 1973).

[59] 461 F.2d 293, 306 (7th Cir. 1972)

[60] Note, however, that EPA may not establish minimum standards of product effectiveness; it can only require the product to be as effective as claimed. S.L. Cowley & Sons Manufacturing Co., Inc. v. EPA, 615 F.2d 1312 (10th Cir. 1980).

[61] See also Continental Chemiste Corporation v. Ruckelshaus, 461 F.2d 335-336 (7th Cir. 1972) (dealing with snake insecticides containing lindane).

In supporting its cancellation orders in that case, EPA relied on a balancing of the risks and benefits based on this language from EDF v. Ruckelshaus[62]:

> The cancellation decision does not turn on a scientific assessment of hazard alone. The statute leaves room to balance the benefits of a pesticide against its risks. The process is a delicate one, in which greater weight should be accorded the value of a pesticide for the control of disease, and less weight should be accorded its value for the protection of a commercial crop. [Footnote omitted.]

The Stearns court admitted that this standard "gives proper effect to the statutory language" in cases involving injury caused by proper use of the product, but rejected it in the case before it where the harm was entirely or primarily due to misuse. There were no claims in this case that the product, when used in compliance with the directions, had caused any injuries. The only reported harm had resulted from willful misuse (suicides) or from wanton recklessness or at least negligent conduct (accidental ingestion).

In the ordinary case of a product which, although properly used, may cause harm to the general public, it seems that even the court in Stearns would permit EPA to use a balancing test as envisioned in EDF v. Ruckelshaus, as long as the test is properly administered. Proper administration includes the identification of conflicting interests so that counterbalancing factors can be assigned appropriate weights. The costs and benefits of all possible decisions, including both cancelling registration and not cancelling it, must be considered.[63]

One of the aspects of this balancing test is that human safety factors, such as prevention of disease, are to be considered more significant than mere economic factors. Clearly, under this test, a major outbreak of a serious disease would tip the scales over a minor economic loss. Similarly, a large economic loss should be more important than a very small chance of a minor disease. However, where the line should be drawn is not specified. Presumably, the courts will defer to EPA's judgment as long as there is some substantial evidence to support its position.

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[62] 439 F.2d 584, 594 (D.C. Cir. 1971).

[63] Continental Chemiste Corporation v. Ruckelshaus, 461 F.2d 331, 336 (7th Cir. 1972) (smoke insecticides containing lindane). "The substantive standards, phrased in terms of protection of the public and impact on living man, require consideration of the aggregate effect of a product's use upon the environment, including not only its potential for harm, but also the benefits which would be lost by removing it from the market."

What kind of evidence or level of proof will be required is also not specified, although the District of Columbia Court of Appeals did indicate, in *EDF v. EPA* (DDT)[64] that "[r]eliance on general data, consideration of laboratory experiments on animals, etc., provide a sufficient basis to support" cancellation of registrations. With respect to what level of proof is required, the Eighth Circuit Court of Appeals had this to say in *Dow Chemical Company v. Ruckelshaus* (2,4,5-T):[65]

> It is not in accord with the statute as amended that the Administrator may issue a cancellation order only and solely upon proofs that the substance involved does not meet the statutory standards evolved for the safety of the public. This, of course, he may do. But he is not so restricted. Since the registrant has a continuing burden of proof to establish that its product is entitled to registration, if the Administrator has a substantial doubt as to safety, it is his duty as well to issue the cancellation order. [Citation omitted.] [Emphasis added.]

The 1975 Amendments to FIFRA, however, overruled the substantial-question-of-safety doctrine with the result that EPA is not required to issue a cancellation notice upon a finding that a substantial question of safety exists. Rather, new procedures -- such as the RPAR discussed in the Regulatory Review -- have been established which allow EPA to look at *both* risks and benefits in a reasonably thorough way prior to cancellation hearings.[66]

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[64] 489 F.2d 1247, 1254 (D.C. Cir. 1973)

[65] 477 F.2d 1317, 1324 (8th Cir. 1973)

[66] See 45 FR 52628, 52631 (August 7, 1980).

FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT--REGULATORY REVIEW

INTRODUCTION

This review covers the regulations for the designation and registration of pesticides under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). Under FIFRA, the Administrator of EPA has the authority to deny or cancel registration of a pesticide, to restrict its use, or to impose specific requirements such as special packaging or labeling if the pesticide poses any unreasonable adverse effects.

As of January 1, 1981, there are approximately 40,000 pesticide formulations registered, including those originally registered under the 1947 Act, and each of these registrations expires every five years.[1] The Agency faces a formidable task of constantly reassessing and updating its decisions as new scientific and technological data is introduced about testing methods and hazards.

Since the enactment of the FIFRA 1972 amendments, few of the procedures involved in registration, cancellation, or reregistration have become final rules. EPA experience with several procedures, changes in FIFRA itself (1978 amendments), and industry reaction to the proposed requirements all have resulted in a still evolving registration policy. However, through such actions as classifying active ingredients for restricted use and banning the use of some pesticides, EPA has taken major regulatory steps under FIFRA's mandate.

OVERVIEW

Major revisions of the regulations are taking place in three areas:

- Registration standards. The Agency has published its Advanced Notice of Proposed Rulemaking to establish a registration standard system,[2] based on 1978 amendments to FIFRA. This would change the registration procedures from registration for each product formulation to a generic approach, where standards will be set for each active ingredient.

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[1] FIFRA Section 6.

[2] 44 FR 76311 (December 26, 1978).

- Data requirements for registration. The 1972 amendments to FIFRA require that EPA publish guidelines for registration. Preliminary Notice of data requirements was published in 1975 and various sections of these have been going through revision since then. Final data guidelines had not been issued as of January 1, 1981.

- RPAR process. This is the procedure by which EPA examines the risks and benefits of using pesticides which are presumed to pose adverse effects on the environment. The Proposed Rules for these procedures, which have been undergoing revision since 1975, were published in August 1980.[3]

Many registration decisions and revisions of registrations are being made on an interim or conditional basis as industry changes its testing methods to comply with these ongoing changes. These changes will be discussed later as we review the registration procedures and criteria for registration.

EPA is authorized to take a variety of regulatory actions with respect to pesticides (See Exhibit 6-2). Most of these actions relate to the registration procedure and FIFRA's key criterion -- unreasonable adverse effects. At the conclusion of the review, we describe how EPA has implemented this criterion with respect to such different actions as labeling, packaging, classification, and RPAR review. Note that EPA's authority to establish tolerance levels (or exemptions) for pesticide residues on raw agricultural commodities derives from the Food, Drug, and Cosmetic Act and receives detailed discussion in the FDA regulatory review.

This review will examine the FIFRA regulations to review which pesticides are designated as hazardous and how these decisions are reached. We discuss the following topics:

- chemical substances comprising pesticides;
- interagency jurisdiction;
- registration procedures and testing requirements;
- unreasonable adverse effects: regulatory criteria;
- pesticides which are regulated for unreasonable adverse effects on the environment; and
- use of pesticide and toxicity categories.

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[3] 45 FR 52628 (August 7, 1980).

CHEMICAL SUBSTANCES COMPRISING PESTICIDES

A pesticide[4] can be a single substance or a mixture of substances. Every pesticide product contains one or more "active" ingredients which by definition produce toxic or behavior altering effects in one or more organisms exposed,[5] and it is well recognized that these ingredients pose hazards to nontarget organisms too. Other harmful chemical substances may be present in a pesticide product, however. Impurities and contaminants may be introduced as the active ingredient is manufactured. In addition, pesticide formulations often include "inert" ingredients, added to improve the usefulness of the product by acting as solvents, bait, dust carriers, fillers, wetting and spreading agents or propellents.[6] While these may be inert as pesticides, they are not necessarily biologically or chemically inert. They may be toxic themselves or may react with other ingredients or packaging materials to produce toxic substances. Some of these inert substances may be used in a whole range of pesticides and thus may accumulate to a far greater concentration in an area than any one active ingredient. Finally, some pesticides are unstable and may form degradation products over time. Since there are several sources of hazardous chemicals in a pesticide formulation, it is important to determine how these different sources are treated in agency regulations.

Until recently, EPA's policy was to register each formulated pesticide product individually. Many pesticide products consist of mixtures of different proportions of the same active ingredients. Every individual product went through the decision process even though similar formulations had already been registered by other producers, resulting in duplication of effort. The Agency has published an Advanced Notice of its new procedure for treating groups of pesticides with similar formulations.[7] Registration standards will be developed for each active ingredient which will summarize the Agency's regulatory position with regard to all pesticide products containing that ingredient. Since the 40,000 registered pesticides contain about 1,500 active ingredients this generic approach will be more efficient. As of January 1, 1981, seven registration standards had been issued.

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[4] A pesticide is defined as either a "substance or a mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, and any substance or mixture of substances intended for use as a plant regulator, defoliant or desiccant." 40 CFR 162.3(ff). These include poisons and repellants, fungicides, herbicides, insecticides, nematicides, rodenticides, slimicides, attractants, and antimicrobial agents.

[5] 40 CFR 162.3(c). Combining pesticide substances can result in "potentiation" or incrasing the effects of each ingredient many-fold.

[6] 40 CFR 162.3(t).

[7] 44 FR 76311 (December 26, 1978).

EXHIBIT 6-2

SUMMARY OF KEY REGULATORY ACTIONS FOR PESTICIDES

Action	Criteria
Deny or cancel registration for some or all uses of pesticide	Unreasonable adverse effects, 40 CFR 162.11
Classify for restricted use only	Toxicity criteria, 40 CFR 162.30
Suspend pesticide registration	Imminent hazard, 40 CFR 162
Review risks posed by pesticide	RPAR criteria, 40 CFR 162
Special labeling standards	Toxicity criteria, 40 CFR 162.10
Special packaging standards	Toxicity criteria, 40 CFR 162.16
Worker protection standards	40 CFR 170
Disposal standards	Adequate margin of safety, 40 CFR 165
Conditional registration	No significant increase in risk of unreasonable adverse effects, 40 CFR 162.18
Establish a tolerance for pesticide on raw agricultural commodities (not under FIFRA)	"Safe" (i.e., not adulterated) 40 CFR 180

INTERAGENCY JURISDICTION

Pesticides are regulated by other agencies which have jurisdiction over the control of hazardous chemicals. DOT, for example, regulates the transport of pesticides. USDA and FDA regulate the amount of pesticide residues allowed in processed foods; EPA sets tolerances for pesticide residues in raw agricultural commodities. Another overlapping area with FDA are pesticides that are also used as drugs.

For example, under 40 CFR 162, a pesticide that is offered solely for human use, and is a "new drug,"[8] as defined by the Federal Food, Drug, and Cosmetic Act (FFDCA), are exempted from the provisions of FIFRA. The process and requirements for obtaining registration for new drugs for human use parallels the requirements of FIFRA. Besides proof of the drugs' safety, composition, effectiveness, and proper labeling, FDA also considers the drugs' impact on the environment through their compliance with the National Environmental Policy Act (21 CFR 6). The intent of this exemption is to lessen the duplication of time and resources by both agencies and the sponsors of the products in registering and regulating the use of the pesticide.[9]

At this time, there is only one type of new drug that is exempted from FIFRA. This is a group of products used as pediculocides for the control of human lice. The active ingredient that qualifies the product as a "new drug" is Lindane (gamma isomer of benzene hexachloride). Other ingredients in the products, which are classified as old drugs and therefore are under dual jurisdiction, are pyrethrins and piperonyl-butoxide. Products under dual jurisdiction, including "old" human drugs (any that do not fit the definition of "new drug"), and new and old animal drugs, must be approved by both agencies, although the major information requirements are handled by one. Interjurisdictional procedures are delineated through Memoranda of Understanding published in the Federal Register. Many jurisdictional problems are still being worked out especially for animal drugs.[10]

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[8] A "new drug" is defined under FFDCA, Section 201(p) as "any drug for human use which is not generally recognized as safe and effective for use under the conditions prescribed or recommended in the labeling." A "new drug" requires a new drug application (NDA), which includes the registration application information.

[9] 43 FR 47215, October 13, 1978, Preamble to Proposed Rules.

[10] Personal communication with Registration Division, Office of Pesticide Programs, U.S. Environmental Protection Agency, 1980.

REGISTRATION PROCEDURES AND TESTING REQUIREMENTS

The registration process and criteria are described at 40 CFR 162.7. The applicant must provide EPA with information to demonstrate that the pesticide will "perform its intended function without unreasonable adverse effects on the environment." The information package supplied by the applicant must include labeling information, the complete chemical formula, appropriate test data, and the proposed use classification. EPA uses applicant data, its own analysis, and any other information available to approve or deny the registration of pesticides. At a minimum, EPA can approve a pesticide registration if the following criteria are met:[11]

- the pesticide is effective for the uses claimed on the label;[12]
- the product is not misbranded and its label complies with the requirements of FIFRA;
- the appropriate test data have been submitted;
- the pesticide will perform its intended function without unreasonable adverse effects on the environment and when used in accordance with widespread and commonly recognized practice will not generally cause unreasonable adverse effects on the environment;[13]
- a tolerance or exemption from a tolerance requirement has been obtained;[14] and

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[11] 40 CFR 162.7(d)(3).

[12] Note that this does not give EPA the authority to set minimum effectiveness standards. FIFRA refers only to the accuracy of the labeling and not to the broader question of overall product effectiveness. Also, section 3(c)(5) allows the Administrator to waive efficacy considerations in the interest of concentrating resources on questions of health and safety. Thus, efficacy data is required only where a human health impact results from ineffectiveness of the product (i.e., hospital disinfectants).

[13] 40 CFR 162.11.

[14] This applies to the amount of pesticide residues which are allowed on feed or food crops. Feed or food crops with residue contamination are considered adulterated under the Federal Food, Drug, and Cosmetic Act; it is unlawful to sell or distribute them unless a regulation has been set establishing a permissible level of residue. These levels or tolerances are set by EPA. See FDA regulatory review in Volume 3.

- the pesticide has been approved under the Federal Food, Drug, and Cosmetic Act (FFDCA) if there are any drug claims on the label.[15]

EPA must balance the benefits of a pesticide against the environmental risks it poses for each of its uses. EPA considers the risks posed to man, beneficial animals, and the environment. With respect to risks posed to human health, the evaluation typically includes consideration of potential hazards to pesticide applicators, farm workers, and oters who might come in contact with the pesteicide during transportation, storage, and application, and afterwards. After this risk evaluation, the agency makes determinations regarding directions for use, warning statements, and other restrictions (e.g., reentry times) necessary to protect man and the environment.

There are specific criteria which signal a pesticide for official (RPAR) review and possible cancellation or denial of registration. A risk benefit synthesis is part of the RPAR process. The Agency can require various steps, from labeling or packaging requirements to restricted use classification, to lower the environmental risk. If the benefits of its use outweighs the risk and there are no substitutes, the pesticide can be registered even if it meets the RPAR criteria for toxicity or environmental damage.

The burden of proving that a pesticide satisfies its registration standard continues to fall on the applicant as long as the registration remains in effect. The Administrator is required to cancel the registration of a pesticide or modify the terms and conditions of registration whenever it is determined that the pesticide no longer satisfies the criteria for registration. A registrant must report information about unreasonable adverse effects as soon as such data becomes available.

Data requirements in support of registration

EPA is currently working on specific guidelines for information to be submitted to support the registration application. These itemize the health and safety data required, and the testing methods to be used in developing the data. Publication of these guidelines was required by the 1972 amendments.[16] An early version of the guidelines was published in 1975; a version with major revisions was published as a Proposed Rule in 1978. As of January 1, 1981, none of the guidelines had been issued as Final Rules. Meanwhile, the guidelines are applied in a case-by-case basis.

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[15] The FFDCA is administered by the Food and Drug Administration. The applicant must show that the drug is safe and effective. Drugs for human use are covered by 21 USC §355; animal drugs are covered under 21 USC §360b. See FDA regulatory review in Volume 3.

[16] FIFRA Section 3(c)(B)(a).

The proposed outline of the guidelines which concern test data is:[17]

Subpart D: Chemistry Requirements: Product Chemistry

Subpart E: Hazard Evaluation: Wildlife and Aquatic Organisms

Subpart F: Hazard Evaluation: Humans and Domestic Animals

Subpart G: Product Performance

Subpart H: Label Development

Subpart I: Experimental Use Permits

Subpart J: Hazard Evaluation: Nontarget Plants and Microorganisms

Subpart K: Exposure Data Requirements

Subpart L: Hazard Evaluation: Nontarget Insects

Subpart M: Data Requirements for Biorational Pesticides

Subpart N: Chemistry Requirements: Environmental Fate

Subpart O: Chemistry Requirements: Residue Chemistry

Subpart P: Data Requirements for Pesticide Disposal

Subpart D sets out the format for reporting the formulation and analytical information on active ingredients, inert ingredients and impurities. It requires data from a battery of microbial bioassay test systems for the formulated product or for each of the components of the formulated product to test for genotoxic activity; requires data on physical and chemical properties of each active ingredient, the formulated product or the manufacturing-use product which are being submitted for registration. (See Exhibit 6-3 for the data requirements.)

Revision of Registration Procedures Now in Progress

The Agency is revising the registration guidelines to incorporate a generic approach called the Registration Standards System. Under this system EPA will evaluate each active ingredient and publish a Registration Standard which would set the regulatory position for all pesticide products containing that ingredient. When the standard is in place, applicants with a new pesticide formulation would have only to demonstrate that the product complies

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[17] Based on March 9, 1980 draft.

EXHIBIT 6-3

SUMMARY OF PHYSICAL AND CHEMICAL PROPERTIES DATA REQUIREMENTS IN § 163.61-10

	Test Substance by Product Type		
Property	Technical or Purer Grade of the Active Ingredient	Manufacturing-Use Product	Formulated Product
1 Color	X		X
2 Physical state	X	X	X
3 Odor	X		X
4 Melting point	X		
5 Boiling point	X		
6 Density or specific gravity	X	X	X
7 Solubility	X		
8 Vapor pressure	X		
9 Dissociation constant	X		
10 Octanol/water partition coefficient	X		
11 pH	X	X	X
12 Stability	X		
13 Oxidizing or reducing action		X	X
14 Flammability		X	X
15 Explodability		X	X
16 Storage stability		X	X
17 Viscosity		X	X
18 Miscibility		X	X
19 Corrosion characteristics		X	X
20 Dielectric breakdown voltage			X

X = Data required

with the requirements of the standard; the Agency will not have to go through the complete decision-making process for each separate pesticide product. After the standard is in place, extensive health and safety data will be necessary only when the registrant is proposing a new use, a new chemical or other deviations from the established standard. EPA will develop standards for groups of active ingredients periodically over the next ten to fifteen years until the pesticides currently in use are covered; thereafter, standards will be published as registrants propose pesticides containing new active ingredients. Seven standards had been issued through January 1, 1981.

How the standards are to be developed is still in question. FIFRA states that currently registered pesticides are to be treated "in the most expeditious manner possible," with priority given to those which result in residues on food or feed crops.[18] Among these, EPA must set priorities. It has identified some key indicators, such as documented adverse effects, type of exposure, and amount of exposure. Another factor in the decision is whether to develop many relatively easy standards or a few difficult ones, or a mixture. EPA is also considering a cluster approach, which groups products with the same or similar uses or which may be used as substitutes for each other if one is found to be unacceptable.[19]

Another consideration is the problem of pesticide formulations and inert ingredients. The application for registration must list all active and inert ingredients contained in the product formulation. The Agency's focus, has been on the active ingredients, since these are included in the product specifically for their toxic effects. An active ingredient and its associated impurities (the combination is known as the "technical chemical") must undergo a full range of acute, chronic and subchronic tests.[20] The inert ingredients do not, under the present registration procedure, routinely go through these tests, but under the proposed guidelines, the formulated product itself will be screened for acute oral, dermal and inhalation toxicity, and for possible chronic effects in a microbial screening test. If the toxicity of the product exceeds the additive toxicity of the individual technical chemicals, further testing of the inert ingredients and contaminants may be required.

EPA has made the decision not to make further testing of the inert ingredients mandatory on a routine basis because of the expense to industry (there are approximately 1,500 inert ingredients used in pesticides currently registered) and its judgment that the additional data produced would not

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[18] FIFRA Section 3(g).

[19] 45 FR 75488 (November 14, 1980).

[20] 43 FR 37339.

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significantly improve the quality of decisionmaking.[21] However, the Agency is aware of the problem of possible accumulation of inert substances and their long range environmental effects. As information about these products becomes available through efforts under TSCA and through biological screening, it has the option of requiring testing of inerts on a case-by-case basis.[22]

Conditional Registration

While the registration standard for a particular active ingredient is being developed, pesticides containing the ingredient can be registered under a program of conditional registration[23] even if all supporting data is not yet available. 40 CFR 162.18(2) requires that use of the product must not cause a "significant increase in the risk of unreasonable adverse effects on the environment".

Conditional registration will allow EPA to convert the registrations of older pesticides without forcing cessation of their use while it gathers the information necessary to complete the Registration Standard for its active ingredients. When the Standard is published, a pesticide's conditional registration will be converted to "unconditional" registration if the pesticide is in compliance with the standard.

Conditional registration also enables EPA to avoid the double standard problem that had plagued its registration program after the 1972 Amendments, when registrants of newly proposed pesticides had to meet more rigorous data standards than had products with the same formulation which were already registered. Since the 1978 amendments, a pesticide which is identical or substantially similar to a currently registered pesticide is eligible for conditional registration.[24]

Renewals of Pesticide Registraton

Pesticides are periodically reviewed to update their registration in light of current scientific and technological knowledge. One way that this is accomplished is through the requirement for reregistration. The registration of a pesticide may be cancelled after five years unless there is a specific request that the registration be continued.[25] The registrant must include any new information and supporting data with the application for reregistration.[26] EPA expects that many registrants will have to furnish new data to comply with the revised requirements for types of data and specific testing methods. The criteria for approval of reregistration are the same as those outlined above for the initial registration and include conditional reregistration where appropriate.

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[21] 43 FR 37340.

[22] Proposed 40 CFR 163.80-3(b)(2)(iv).

[23] See 40 CFR 162.18-1 through 162.18-5 (44 FR 27932, May 11, 1979).

[24] FIFRA Section 3(c)(7)(A).

[25] FIFRA Section 6(b).

REGULATORY CRITERIA

Regulatory criteria are discussed in more detail in the following sections:

- Criteria for banning or limiting the use of a pesticide discusses the RPAR criteria and summarizes current actions under this process.
- Classification for general or restricted use outlines the criteria and requirements for classification and the different ways a pesticide may be classified.
- Other specific pesticide requirements, such as special labeling, packaging, and worker protection.

Criteria for Banning or Limiting Use of a Pesticide

RPAR criteria and review. EPA developed the RPAR process to examine pesticide uses which might not meet registration requirements. When there is reason to suspect that a use of a pesticide will cause unreasonable risk to the environment, the Administrator can make a rebuttable presumption against registration or against continued registration of this pesticide. This sets in motion a process which brings together the interested public, industries, and government agencies to review the available evidence on both hazards and benefits of use of the pesticide.

In 1975 under regulations to implement the 1972 FIFRA amendments, EPA developed the criteria which would bring a product into the RPAR process.[27]

The risk criteria concern the following:

1. Acute toxicity to humans, domestic animals or wildlife
2. Chronic Toxicity
    A. Oncogenic
    B. Mutagenic

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[26] See 40 CFR 162.6(b)(5).

[27] 40 CFR 162.11.

3. Other Chronic Effects
    A. Reproductive
        (1) Fetotoxicity
        (2) Teratogenicity
    B. Spermatogenicity
    C. Testicular Effects

4. Significant reduction in wildlife, reduction in endangered species, and reduction in non-target species.

5. Lack of Emergency Treatment or Antidote.

These general criteria have been expanded to specify levels of toxicity which result in a rebuttal presumption against registration or continued regulation (Exhibit 6-4). These criteria are a screening mechanism to determine which pesticides must be examined more closely before re-registration. The general principles of the RPAR process are described below.

If the pesticide meets the RPAR criteria, the burden of proof is on the registrant to rebut the presumption against registration. The registrant may do this by showing:

- that under the terms of the registration proposal the anticipated exposure to the applicator or user and non-target populations "is not likely to result in any significant acute adverse effects," or

- that the pesticide would not persist or accumulate in man or the environment to levels "likely to result in any significant chronic effects," or

- that the determination that the pesticide meets or exceeds the criteria for risk is in error.[28]

The purpose of the rebuttal presumption is to examine the individual characteristics of the particular pesticide and the particular types and levels of exposure that might result from its use. The registrant can bring in evidence to show that the levels of exposure required to cause acute or chronic effects will not result from the proposed uses. Alternatively it may be shown that risks can be minimized and brought into acceptable levels by restrictions on use. The registrant must show that the benefits of each use of the pesticide exceed the risks of use. The registrant can introduce evidence on economic, social and environmental benefits.

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[28] 40 CFR 162.11(a)(4)

EXHIBIT 6-4

RPAR CRITERIA

A rebuttable presumption against registration arises against a pesticide which meets or exceeds any of these criteria from 40 CFR 162.11(a)(3):

1. Acute Toxicity
   - human and domestic animals
     - Oral LD(50) • 40 mg/kg or less
     - Dermal LD(50) • 6 g/kg or less
     - Inhalation LC(50) • 0.04 mg/liter or less
   - wildlife
     - mammals • leaves residue equal to or greater than the acute oral LD in representative test animals[1]
     - birds • leaves residue equal to or greater than the subacute dietary LC in representative test animals
     - aquatic • reaches concentration of more than 1/2 acute LC for representative test animals[1]
2. Chronic Toxicity
   - induces oncogenic effects in mammals or humans
   - induces mutagenic effects
   - produces other chronic or delayed toxic effects
   - results in local, regional or national population reductions in nontarget species
   - results in fatality to members of endangered species
3. Lack of Emergency Treatments--Has no known antidotal, palliative or first aid treatments

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[1] Specified in proposed Regulation guidelines.

If the Administrator determines that the presumption against registration has been overcome and the pesticide otherwise meets with agency requirements, EPA will register the pesticide or continue its registration. If there is no evidence submitted in rebuttal or if the Administrator finds that the evidence submitted does not meet the burden of proof, the Administrator can either move to deny or cancel the registration, or hold hearings to determine whether the registration should be cancelled or denied. The decision to hold further hearings rather than to directly issue a notice of cancellation or denial may be influenced by any economic, social and environmental evidence suggesting that the benefits may outweigh the risks.

RPAR Process. Shortly after the 1975 regulations went into effect, EPA modified the procedures used to examine pesticides alleged to pose unreasonable risk. The changes were based on an *ad hoc* review of agency procedures and on the 1975 amendments to FIFRA. In its 1975 amendments Congress required that the cancellation actions be reviewed by two groups before publication: (1) by the Secretary of Agriculture who would also review an analysis of the impact on the agricultural economy, and (2) by a Scientific Advisory Panel. The review panel pointed out that the trial-type procedures used in gathering information during the RPAR process had inhibited the participation of the public and the other federal agencies and did not provide the right atmosphere for input by program offices into the decisionmaking process.

The effect of these changes was to shift the emphasis of the RPAR review from a process of information-gathering during formal hearings into a more informal process where hearings are held only if a decision is challenged or after a notice of denial or cancellation of registration is issued. Whereas previously the consideration of benefits, and the weighing of risks and benefits, took place in the hearings, this is now done as a part of the RPAR process before a notice of denial or cancellation is issued. EPA has recently proposed regulations[29] which incorporate these changes and reflect agency procedures developed since 1975. The regulations outline specific procedures for the RPAR process. The major steps are discussed below.

Pesticides which meet or exceed risk criteria based on evidence of "validated tests" or "other significant evidence" are nominated for RPAR. This wording reflects the the move away from the less rigorous "substantial evidence of harm" language used in the DDT and Aldrin/Dieldrin decisions. Nomination cannot be based on unsubstantiated evidence or on data from misuse of pesticides. The risk criteria remain the same as in earlier versions; the preamble of the proposed regulations mentions that some suggestions for change in the RPAR criteria have been suggested but that the Agency will approach this issue separately from the issue of changes in the RPAR procedures. The

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[29] 45 FR 52628 (August 7, 1980).

Administrator may also nominate a pesticide which does not meet these specific risk criteria if there is concern that the Agency should look at a new area where risks may outweigh the benefits. This gives the Agency some discretion to look at pesticides which may pose an unreasonable adverse effect in ways not anticipated under the current risk criteria.

The chemicals which go into a pre-RPAR review are examined by agency scientists and contractors to determine if the risk criteria have been met. The registrant is notified and may be asked to supply more information. The Agency develops a preliminary position on the potential risk which is described in a position document (PD 1). If the criteria are met, a formal Notice of Presumption Against Registration is published in the Federal Register.

After the RPAR is issued, interested parties may submit data to rebut the Agency's presumptions against registration. The criteria for rebuttal are:

- that the determination by the Agency was in error;
- that when used under the conditions of its registration, the pesticide use will not pose a significant risk;
- that the risks posed by the pesticide are not unreasonable taking into account the economic, social and environmental costs and benefits of the pesticide use; the registrant should show:
    (1) that the benefits outweigh the risks, and
    (2) that the risks cannot be further reduced without unreasonable costs.

If the presumption is successfully rebutted, the Agency publishes a position document (PD 2) and the pesticide returns to the registration process. It is possible that some uses of a pesticide can be successfully rebutted while others must be restricted in some way.

If no evidence is presented for rebuttal, or the presumption is not successfully rebutted, the Agency develops a position document (PD 2/3) which outlines the risks, benefits and support for the various regulatory options which it can pursue. These range from cancellation or denial to minor labeling changes or restrictions in use. This document is support for the Preliminary Notice of Determination which outlines the regulatory actions the Agency has temporarily decided to implement. As shown in Exhibit 6-5, the Agency has published a Preliminary Notice of Determination for nine pesticides, as of January 1, 1981.

If it is determined that some modifications in the conditions of registration would remedy the adverse effect, the Administrator may modify the terms. For instance, Section 6(b) of FIFRA specifically directs the Administrator to consider restriction of a pesticide's use as an alternative to cancellation of a registration after considering the impact of cancellations on the agricultural economy.

The Secretary of Agriculture and the Scientific Advisory Panel review the Agency decision. It is Agency policy to solicit public comment at this stage. After considering input from these sources, the Agency adopts a final position (PD 4) and publishes a Final Notice of Determination which outlines its decision on regulatory action. The Agency has published a Final Notice of Determination for eight pesticides, as shown in Exhibit 6-5, through January 1, 1981.

Classification for General or Restricted Use

Classification Criteria. A pesticide may be classified for general use or for restricted use. A general-use pesticide is sold with no restrictions on who can use it. A restricted use pesticide can be limited to use by, or under the supervision of, a certified applicator. (These are individuals who have met federal and/or state requirements by demonstrating basic competence and knowledge about the environment, pesticide use, antidotes and treatments.) Pesticide use can also be limited by other restrictions such as seasonal or regional limitations, use in approved pest management programs, or a requirement for monitoring residue limits after use. Restricting the use of a pesticide is one way by which EPA can reduce environmental risk to an acceptable level.

To be classified as a general-use pesticide, the product must not surpass basic standards for human toxicity and harm to non-target organisms. These standards vary depending on the intended use of the product: domestic or non-domestic, indoor or outdoor use. The specific standards are given in Exhibit 6-6 based on 40 CFR 162.11(c). In addition the Administrator can classify a pesticide for restricted use even though it would otherwise meet the criteria for general use if the product "may pose a serious hazard to man or the environment which can reasonably be prevented by" this restriction.[18]

Classification by Active Ingredients or Groups. The optional procedures described at 40 CFR 162.30 provide EPA with the regulatory basis for pesticide classification by active ingredient. Following normal regulatory procedures (i.e. proposal, final, revised), EPA classifies, for restricted use only, some or all uses of: (1), A group of products which contain common active ingredients; or (2), a particular concentration range, formulation, or

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[18] 40 CFR 162.11(c)(4).

EXHIBIT 6-5

PESTICIDES SELECTED FOR RPAR REVIEW

Pesticide		Notice of Determination	
		Preliminary	Final
Amitraz, 42 FR 18299 (April 6, 1977)	RPAR COMPLETED	X	X
Benomyl, 42 FR 61788 (December 6, 1977)		X	
BHC (benzene hexachloride), (See Lindane) 41 FR 46024 (October 19, 1976)			
Cadmium, 42 FR 56574 (October 26, 1977)			
Calcium arsenate, 43 FR 48267 (October 18, 1978)			
Captan, 45 FR 54938 (August 6, 1980)			
Carbon Tetrachloride, 45 FR 68551 (October 15, 1980)			
Chlorobenzilate, 41 FR 21517 (May 26, 1976)	RPAR COMPLETED	X	X
Chloroform, 41 FR 14588 (April 6, 1979)			
Coal tar, 43 FR 48154 (October 18, 1978)			
Creosote, 43 FR 48154 (October 18, 1978)			
DBCP (dibromochloropropane), 42 FR 48026 (September 22, 1977)	RPAR COMPLETED	X	X
Diallate, 42 FR 27699 (May 31, 1977)		X	
Dimethoate, 42 FR 45806 (Septemer 22, 1977)	RPAR COMPLETED	X	X
EBDC (ethylenebisdithiocarbamates), 42 FR 40618 (August 10, 1977)			
Endrin, 41 FR 31316 (July 27, 1976)	RPAR COMPLETED	X	X
EPN (ethyl p-nicophenyl thionobenzenephosphonate), 44 FR 54384 (September 18, 1979)			
Ethylene dibromide, 44 FR 63134 (December 14, 1977)		X	

Source: Special Pesticide Review Division Quarterly Status Report, February, 1981.

EXHIBIT 6-5 (continued)

PESTICIDES SELECTED FOR RPAR REVIEW

Pesticide		Notice of Determination	
		Preliminary	Final
Ethylene oxide, 43 FR 3800 (January 27, 1978)			
Inorganic arsenicals, 43 FR 42867 (October 18, 1978)			
Kepone (Chlordecone), 41 FR 12333 (March 25, 1976)			X
Lead arsenate, 43 FR 48267 (October 18, 1978)			
Lindane, 42 FR 9816 (February 18, 1977)		X	
Maleic hydrazide, 42 FR 56920 (October 28, 1977)			
PCNB (pentachloronitcobenzene), 42 FR 61894 (December 7, 1977)			
Pentachlorophenol, 43 FR 48443 (October 18, 1978)			
Pronamide, 42 FR 32302 (June 24, 1977)	RPAR COMPLETED	X	X
Silvex, 43 FR 17116 (April 21, 1978)	RPAR COMPLETED	X	X
Sodium arsenate, 43 FR 48267 (October 18, 1978)			
Sodium fluoroacetimide (1081) 41 FR 52792 (December 1,1976)	RPAR COMPLETED		
Sodium fluoroacetate (1080) 41 FR 52792 (December 1, 1976)			
Sodium pyroarsenate, 43 FR 48267 (October 18, 1978)			
Strychinine, 42 FR 2714 (January 13, 1977)		X	
Strychinine sulfate, 42 FR 2714 (January 13, 1977)		X	
2,4,5-T, 43 FR 17116 See Silvex (April 21, 1978)		X	X
2,4,5-TCP, 42 FR 41268 (September 15, 1978)			
Thiophonate methyl, 42 FR 61970 (December 7, 1977)		X	
Toxaphene, 42 FR 26860 (May 27, 1977)			
Trifluralin, 44 FR 50911 (August 30, 1979)			

combination of these common active ingredients.[31] A use is classified as restricted if the EPA determines that the incremental risks of unrestricted use outweigh the incremental benefits of unrestricted use.[32] Exhibit 6-7 lists those active ingredients which have been classified for restricted use under this procedure.

Classifying substances by active ingredients does not remove the requirement for registration of a product, but allows certain limitations to take effect without the lengthy risk/benefit analysis and test data required for registration and the RPAR process. Classification by rulemaking is based only on an analysis of the incremental costs and benefits of restricted use, including the specific criteria (Exhibit 6-6) ncessary for general use classification.[33]

OTHER PESTICIDE REGULATIONS

Labeling Regulations. Registered pesticide products are required to bear labels containing adequate directions for use, warnings and cautions designed to prevent injuries, and any additional restrictions necessary to prevent illegal contamination of food or feed.[34]

Warnings and precautionary statements are required for pesticides according to their "Toxicity Category", the type of toxic effects, and the first aid required. Human Toxicity Categories are based upon the highest hazard shown by any of five indictors: Oral LD_{50}, Inhalation LC_{50}, Dermal LD_{50}, eye effects and skin effects. Exhibit 6-8 shows the criteria for the toxicity categories.

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[30] 40 CFR 162.11(c)(4).

[31] 40 CFR 162.30(a).

[32] 40 CFR 162.30(b).

[33] 40 CFR 162.31(b).

[34] Labeling restrictions to prevent food or feed contamination are generally based on the period of time (e.g., 14 days before harvest) required for the reduction of pesticide residues to approved levels or "tolerances." Prior to registration of pesticides for use on crops, a tolerance or other clearance under the Food, Drug, and Cosmetic Act is required for any residues which can reasonably be expected to remain on food or feed at harvest. See FDA regulatory and statutory reviews in Volume 3.

EXHIBIT 6-6

CRITERIA UNDER WHICH A PESTICIDE MAY BE CLASSIFIED FOR GENERAL USE

	Application	
	Domestic	Nondomestic
acute dermal LD_{50}	2,000mg/kg	200mg/kg
		16g/kg as detected for use as mist or spray
inhalation LC_{50}	2mg/liter	0.2mg/liter
eye injury	no corneal opacity eye irritation reversible within seven days	noncorrosive corneal opacity reversible within seven days
skin irritation	no more than moderate within 72 hours	noncorrosive, no more than severe within 72 hours
oral LD_{50}	1.5g/kg as detected for use	N/A
subacute, chronic or delayed effects from single or multiple exposure	minor only	minor only

Outdoor application: A pesticide must meet the appropriate criteria above for domestic or nondomestic use and:

Leaves residue

- less than one-fifth acute LD_{50} in mammalian test animals,
- less than one-fifth subacute dietary LC_{50} in avian test animals, and
- less than one-tenth acute LC_{50} for aquatic test animals.

Causes only minor adverse effects on physiology, growth, population levels or reproductive rate of nontarget organisms.

EXHIBIT 6-7

ACTIVE INGREDIENTS CLASSIFIED FOR RESTRICTED USE[a]

Active Ingredient	Proposed	Finalized
Acrolein	9/1/77	2/9/78
Acrylonitrile	9/1/77	2/9/78
Aldicarb	9/1/77	2/9/78
Allyl alcohol	9/1/77	2/9/78
Aluminum phosphide	9/7/77	2/9/78
Azinphos methyl	9/1/77	2/9/78
Calcium cyanide	9/1/77	2/9/78
Carbofuran	8/1/79	-
Carbon disulfide	8/1/79	-
Chloropicrin	8/1/79	1/12/81
Cycloheximide	8/1/79	1/12/81
Demeton	9/1/77	2/9/78
Dicrotophos	8/1/79	1/12/81
Disulfoton	8/1/79	-
Endrin	9/1/77	2/9/78
EPN	8/1/79	1/12/81
Ethoprop	8/1/79	-
Ethyl parathion	9/1/77	2/9/78
Fenamiphos	8/1/79	-
Fensulfothion	8/1/79	-
Fenthion	8/1/79	-
Fluoroactamide/1081	9/1/77	2/9/78
Fonofos	8/1/79	-
Hydrocyanic acid	9/1/77	2/9/78
Methamidophos	8/1/79	1/12/81
Methidathion	8/1/79	1/12/81
Methomyl	9/1/77	2/9/78
Methyl bromide	9/1/77	2/9/78
Methyl parathion	9/1/77	2/9/78
Mevinphos	9/1/77	2/9/78
Monocrotophos	8/1/79	-
Nicotine (alkaloid)	8/1/79	1/12/81
Oxamyl	8/1/79	-
Paraquat (dichloride) and paraquat bis (methylsulfate)	9/1/77	2/9/78
Phorate	8/1/79	-
Picloram	9/1/77	2/9/78
Sodium cyanide	9/1/77	2/9/78
Sodium fluoroacetate	9/1/77	2/9/78
Strychnine	9/1/77	2/9/78
Sulfotepp	9/1/77	2/9/78
Temephos	8/1/79	-
Tepp	9/1/77	2/9/78
Zinc Phosphide	8/1/79	1/12/81

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[a] Some or all formulations may be restricted - See 40 CFR 162.31 for details.

EXHIBIT 6-8

HUMAN HAZARD TOXICITY CATEGORIES FOR LABELING

Hazard Indicators	I	II	III	IV
Oral LD50	0-50 mg/kg	50-500 mg/kg	500-5000 mg/kg	Greater than 5000 mg/kg
Inhalation LC50	0-.2 mg/kg	.2-2 mg/1	2-20 mg/1	Greater than 20 mg/1
Dermal LD50	0-200 mg/kg	200-2000 mg/kg	2,000-20,000 mg/kg	Greater than 20,000 mg/kg
Eye Effects	Corrosive corneal capacity not reversible within 7 days	Corneal capacity reversible within 7 days, irritation persisting for 7 days	No corneal capacity irritation reversible within 7 days	No irritation
Skin Effects	Corrosive	Severe irritation at 72 hours	Moderate irritation at 72 hours	Mild or slight irritation at 72 hours
Human Hazard Signal Words (shown on front panel)	Danger	Warning	Caution	Caution

Besides the signal words shown in Exhibit 6-8 (i.e., Danger, Poison, etc.) front panel labels must also include child hazard warnings (applicable to all pesticide labels), a statement of practical treatment, (applicable to the specific pesticide and its effects), and in some cases, other precautionary statements. Other precautionary statements include statements regarding environmental hazards and physical or chemical hazards. Environmental hazards are rated according to their effect upon wildlife, fish, birds, polluting insects, and other non-target organisms. Exhibit 6-9 contains the examples of pesticide hazards and the accompanying required hazard statements that are included in the regulations.

In addition, on June 5, 1980, the Agency announced a Label Improvement Program under which it will evaluate registrations to see if significant improvements in health or safety can be made by labeling changes. This program allows the agency to look at groups of pesticides which are not up for reregistration but for which newly available data indicate a possible hazard. This will not be a complete evaluation of risks and benefits, which is part of the registration/reregistration process, but allows the Agency to see if changes in labeling and/or instructions will reduce the risks of a particular pesticide use. Changes made at this time will not affect the decisions to be made during the normal reregistration process, where the overall impacts of the pesticide use are evaluated.

Special Packaging Regulations. Under Section 25(c)(5) of FIFRA, EPA requires special packaging for certain toxic pesticides to protect children and adults from serious injury or illness. Pesticides requiring special packaging are those classified for general use (restricted uses are dealt with on a case-by-case basis), that are labeled for residential use, and that meet certain toxicity criteria, which are listed below:[35]

- acute dermal LD(50) of 2,000 mg/kg or less;
- acute inhalation LC(50) of 2 mg/l or less;
- corrosive to the eye;[36]
- corrosive to the skin;[37]

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[35] 40 CFR 162.16(c)(2).

[36] Defined as causing irreversible destruction of ocular tissue or corneal involvement or irritation persisting for 21 days or more.

[37] Defined as causing tissue destruction into the dermis and/or scarring, or severe skin irritation (erythema or edema) at 72 hours.

EXHIBIT 6-9

LABELING: ENVIRONMENTAL HAZARDS CRITERIA[1]

	Hazard Indicator/Category	Required Labeling
A	Outdoor pesticide containing an active ingredient with a mammalian acute LD(50) of 100 or less; or avian acute oral LD(50) of 100 mg/kg or less; or avian subacute dietary LC(50) of 500 ppm or less.	"The Pesticide is Toxic to Wildlife"
B	Outdoor pesticide containing an active ingredient with a fish acute LC(50) of 1 ppm/or less.	"This Pesticide is Toxic to Fish"
C	Pesticides for foliar applications toxic to pollinating insects	Appropriate label cautions
D	Accident or field studies demonstrate potential bird, fish, or mammal fatalities.	"This pesticide is extremely toxic to wildlife (fish)."
E	All outdoor uses other than aquatic uses.	"Keep out of lakes, ponds, or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

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[1] 40 CFR 162.10(h)(2).

- acute oral LD(50) of 1.5 g/kg or less;
- other toxicological data, use history, accident data, or other evidence showing that special packaging could reduce serious hazards.

The required packaging is based on effectiveness testing procedures outlined by Consumer Product Safety Commission protocol.[38] Exemptions, which are dealt with case-by-case, are applicable to all products of identical or substantially similar composition and uses.

Worker Protection Standards. Worker protection standards are included in the regulations to protect farm workers from exposure to hazardous pesticides. These standards are issued pursuant to Section 25 of FIFRA. The standards include recommendations for reentry times, warnings, protective clothing, and special precautions. Besides the general standard for reentry, which requires the owner to wait until sprays have dried or dusts have settled before allowing farm workers to enter the field, certain pesticides have been given either exemptions or a longer reentry time. Pesticides with the active ingredients listed below require at least the time interval listed opposite for reentry.[39]

Pesticide	Hours
1. Ethyl parathion	48
2. Methyl parathion	48
3. Guthion	24
4. Demeton	48
5. Azodrin	48
6. Phosalone	24
7. Carbophenothion	48
8. Metasystox-R	48
9. EPN	24
10. Bidrin	48
11. Endrin	48
12. Ethion	24

Criteria and Standards for Disposal of Pesticides. In the case of pesticides whose registrations have been cancelled after having first been suspended to avoid imminent hazard, EPA must accept responsibility for their management and ultimate disposal. The owner, however, must first make an effort to return the pesticide to the manufacturer, or to another agent capable of using the product. To carry out its responsibilities, EPA has established recommended procedures for the disposal and storage of pesticides and pesticide-related wastes.[40]

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[38] The special packaging must not be detrimental to the integrity of the product; must show a child resistant effectiveness of at least 85 percent without, and 80 percent with, a demonstration; and an adult-use effectiveness of at least 90 percent.

[39] 40 CFR 170.3(b)(2).

FIFRA, Sections 19(a) and 25(a), gives EPA the authority to establish regulations and procedures for the storage and disposal of pesticides or pesticide containers. The procedures in 40 CFR 165.1-165.10 are mandatory for EPA disposal operations only and are subject to changes and revisions as necessary to "protect public health and environment" with an "adequate margin of safety".[41] Acceptable disposal procedures are determined by the composition and toxicity of each type of pesticide. Recommendations for disposal are based on the type pesticide, type of container, and disposal method. Pesticides are classified according to their toxicity and persistence in the environment: (1) organic mercury, lead, arsenic, cadmium, and organic pesticides; (2) other metallo-organic pesticides; and (3) nonmetallic organic pesticides.[42] Each of these categories have disposal options, including incineration, landfill, or soil injection with special limitations outlined in the regulations. Storage recommendations take into account safety measures, sites of storage, separation of products, and fire control.[43]

SUMMARY OF PESTICIDES REGULATED FOR HAVING UNREASONABLE ADVERSE EFFECTS

EPA has cancelled the registration of the following pesticides for all or most uses:

Pesticide	Federal Register Notice
DDD (TDE)	36 FR 5254 (3/18/71)
DDT (Most uses)	37 FR 13369 (7/7/72)
Aldrin/Dieldrin (most uses)	39 FR 37216 (10/18/74)
Chlordane/Heptachlor (most uses)	39 FR 41298 (11/26/74)
Mirex	41 FR 56703 (12/29/76)
Chlordecone/Kepone	42 FR 18885 (4/11/77)

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[40] 40 CFR 165.1-165.10.

[41] 40 CFR 165.2(b).

[42] 40 CFR 165.8-10.

[43] Storage recommendations are applicable to Toxicity Categories I and II only. Toxicity categories are determined by several hazard indicators such as corrosivity and LD_{50}, and are outlined at 40 CFR 162.10(h)(1) Labeling Requirements (see Exhibit 6-8).

The Agency has issued a Notice of Intent to Cancel on the following pesticides:

Pesticide	Federal Register Notice
DBCP/1,2-dibromo-3-chloropropane[44]	44 FR 65135 (10/29/79)
2,4,5-T/Silvex	44 FR 72316 (3/15/79)
Amitraz/Baam	44 FR 32736 (6/7/79)
Chlorobenzilate	44 FR 9547 (2/13/79)
Endrin	44 FR 43631 (7/25/79)

After the publication of a Notice of Intent to Cancel, the registrant or any person adversly affected by the decision may request a hearing to review objections. Hearings for 2,4,5-T/Silvex began on March 14, 1980.

A registrant may withdraw an application for registration or voluntarily cancel registration of a pesticide use.[45] The registration of the following ingredients has been voluntarily cancelled:

Pesticide	Federal Register Notice
Acrylonitrile (3 products)	43 FR 26310 (6/19/78)
Aramite	42 FR 19209 (4/12/77)
Arsenic trioxide	42 FR 45944 (9/13/77)
Basic copper arsenate	42 FR 18422 (4/7/77)
Benzac/Bentazon	42 FR 39977 (8/8/77)
BHC (benzene hexachloride) (Lindane)	43 FR 31432 (7/21/78)
Chloranil	42 FR 3702 (1/19/77)
Chlordecone/Kepone (products of 6 formulators)	42 FR 38205 (7/27/77)
Copper acetoarsenite (some products)	42 FR 18422 (4/7/77)
Erbon	45 FR 58770 (10/4/80)
Monuron (some products)	42 FR 41320 (8/16/77)
OMPA/octamethylpyrophosphoramide	41 FR 21859 (5/28/76)
Perthane (many products)	45 FR 41694 (6/20/80)
Phenarsazine chloride	42 FR 59776 (11/21/77)
Safrole	42 FR 11039 (2/25/77)
"	42 FR 16844 (3/30/77)
"	42 FR 29957 (6/10/77)
Sodium arsenite (two products)	43 FR 48267 (10/18/78)
Strobane	41 FR 26607 (6/28/76)
Trysben	43 FR 5782 (2/9/78)

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[44] EPA suspended uses of these pesticides at the time of the cancellation notice. Under a Notice of Intent to Cancel a pesticide, use of the pesticide can continue until hearings, if requested, are complete. Under Suspension orders, which must be accompanied by a Notice of Intent to Cancel, further use of the pesticide is forbidden until the cancellation issue is resolved. FIFRA Section 6(c).

[45] 40 CFR 162.7(f)(2)(ii).

PESTICIDE AND TOXICITY CATEGORIES

Categorization of Pesticides. The EPA must deal with the constant task of updating testing procedures and technical information on pesticides, as well as the continued registration of new and reregistration of old pesticides. The EPA has taken some steps to simplify the registration process including classification by active ingredient, and most recently, the proposed registration standards. The standards have evolved from experience gained in trying to register each product, even similar formulations, individually. Registration standards decrease duplicative efforts by condensing 40,000 pesticide products into 1500 active ingredients.

Many of the most common pesticides fall into three chemical groups:

(1) Organic phosphates (e.g., parathion, EPN, malathion, diazinon)

(2) Chlorinated hydrocarbons (e.g., aldrin, dieldrin, DDT, chlordane, heptachlor, kepone)

(3) Carbamates (e.g., carbyl)

Other important pesticide groups include inorganic arsenics, cyanides, coumarins, indandiones, organic acids, and derivates. Each group has its own special health hazards, acute and/or chronic.

In an effort to simplify and standardize as much as possible, pesticides are categorized by the EPA. In some cases, EPA has assigned pesticides to categories by their effects (e.g., use classification, toxicity categories) in others, by their physical structure.

For instance, all pesticides are divided into three categories in the recommendations for disposal.[48] These three categories are:

(1) organic mercury, lead, cadmium, and arsenic containing compounds and inorganic compounds;

(2) other metallo-organic compounds; and

(3) organic compounds.

These groupings are useful in establishing disposal procedures because members of a group require similar disposal and precautions. However, these groups may or may not be useful in, for instance, establishing tolerances or for labeling purposes. Instead, pesticide tolerances on raw agricultural commodities are set by the nature of their residues; some pesticides are grouped according to their pharmacological effects: chlorinated organic pesticides, arsenic containing chemicals, metallic diothiocarbamates, cholinesterase-inhibiting pesticides, and dinitrophenols.[47] Exhibit 6-10 outlines these categories.

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[48] 40 CFR 165.1.

EXHIBIT 6-10

ONE CATEGORIZATION OF PESTICIDES

Disposal Groupings	Tolerance Groups That Would Be Included
I. Organic (nonmetallic) pesticides	a. Chlorinated organic pesticides b. Dinitrophenols c. Diothiocarbonates (partially)
II. Metallorganic (except lead, cadmium, mercury and arsenic) pesticides	a. Diothiocarbonates (partially) b. Copper compounds (partially)
III. Organic mercury, lead, cadmium and mercury compounds, and inorganic pesticides	a. Arsenic containing compounds

Toxicity Criteria. The overriding FIFRA criterion of "unreasonable adverse effects" needs further specification when used in regulatory efforts. Although the reasonableness or unreasonableness of the risks posed by the pesticide must be determined through a case-by-case balancing of the risks and benefits, it is feasible and desirable to establish generic toxicity criteria to identify "adverse effects." Likewise, EPA has adopted generic toxicity criteria for the RPAR review process. Unlike the other generic toxicity criteria, the RPAR criteria are rebuttable and do not predispose regulatory outcomes in the absence of a cost-benefit balancing. Hazard classifications have been developed for other toxics programs (EPA and non-EPA) and are compared in Volume I of this report.

As shown in Exhibits 6-11 through 6-15, toxicity parameters for FIFRA are somewhat standardized across regulatory categories. Labeling and use classifications, for instance, generally utilize the same toxicity categories. However, EPA has let the purpose and need of the standard determine the appropriate toxicity criteria even at the necessary cost of some inconsistency. This can be clearly seen in the Exhibits.

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[47] 40 CFR 180.3.

EXHIBIT 6-11

FIFRA HUMAN TOXICITY CRITERIA (ACUTE DERMAL LD_{50})

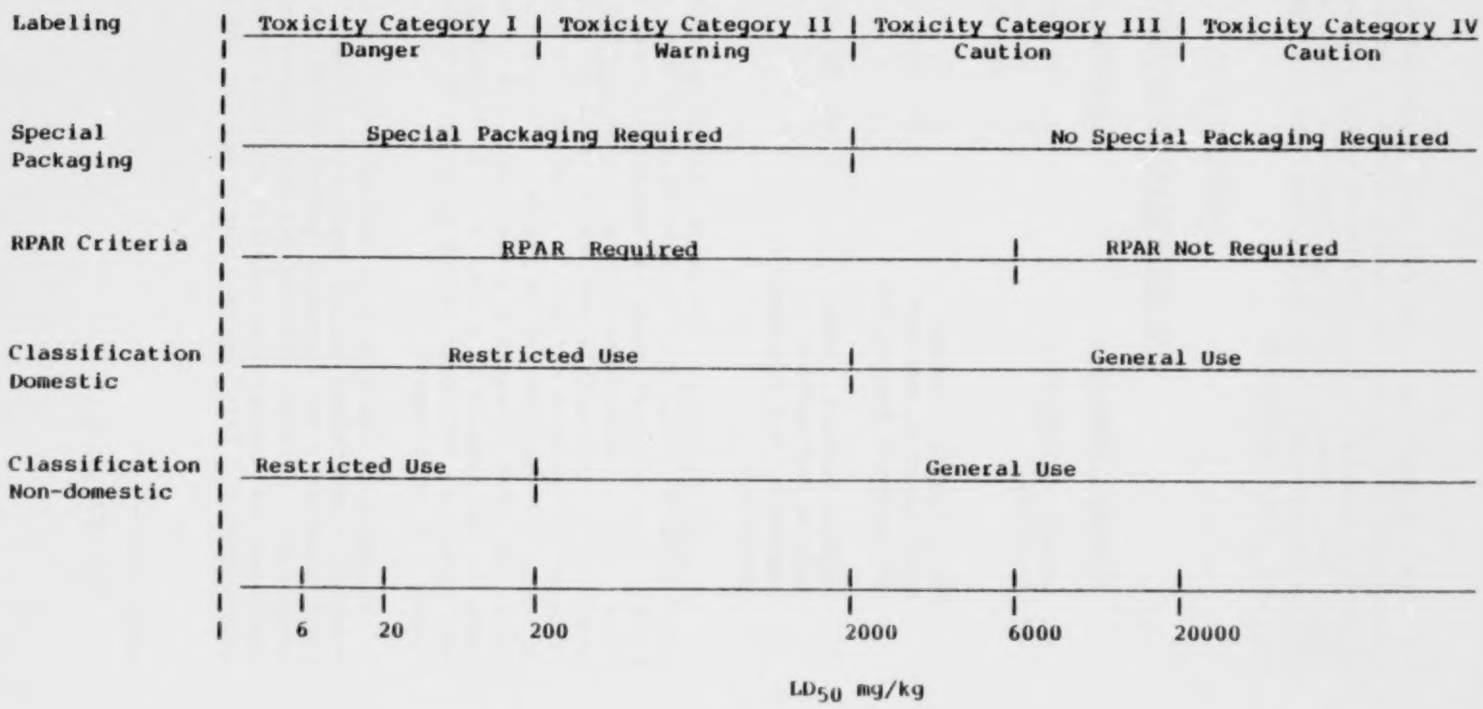

Labeling
Toxicity Category I
Danger
Toxicity Category II
Warning
Toxicity Category III
Caution
Toxicity Category IV
Caution
Special Packaging
Special Packaging Required
No Special Packaging Required
RPAR Criteria
RPAR Required
RPAR Not Required
Classification Domestic
Restricted Use
General Use
Classification Non-domestic
Restricted Use
General Use
6
20
200
2000
6000
20000
LD50 mg/kg

EXHIBIT 6-12

FIFRA HUMAN TOXICITY CRITERIA (EYE EFFECTS)

Labeling	Toxicity Category I	Toxicity Category II	Toxicity Category III	Toxicity Category IV
	Corrosive, corneal opacity not reversible within 7 days	Corneal opacity reversible within 7 days, irritation persists for 7 days	No corneal opacity, irritation reversible within 7 days	No irritation
Special Packaging	Corrosive[a/] Requires Special Packaging	Does not Require Special Packaging		
RPAR Criteria	N/A			
Classification Domestic	Restricted Use		General Use same as Toxicity Category III above	
Classification Non-domestic	Restricted Use	General Use Same as Toxicity Category II above		

Most Corrosive ... Least Corrosive

[a/] The "corrosive" category for special packaging is not exactly the same as the labeling Toxicity Category I. It is defined as: "corrosive, (irreversible destruction of ocular tissue), or causing corneal involvement for 21 days or more."

EXHIBIT 6-13

FIFRA HUMAN TOXICITY CRITERIA (SKIN EFFECTS)

Labeling	Toxicity Category I	Toxicity Category II	Toxicity Category III	Toxicity Category IV
	Corrosive	Severe irritation of 72 hours	Moderate irritation at 72 hours	Mild or slight irritation at 72 hours
Special Packaging	Corrosive (causes tissue destruction and/or scarring); causes severe skin irritation at 72 hours			
	Special Packaging Required		Special Packaging Not Required	
RPAR Criteria	N/A			
Classification Domestic	Restricted Use		General Use Same as Toxicity Category III above	
Classification Non-domestic	Restricted Use	General Use Same as Toxicity Category II above		
	Most Corrosive			Least Corrosive

EXHIBIT 6-14

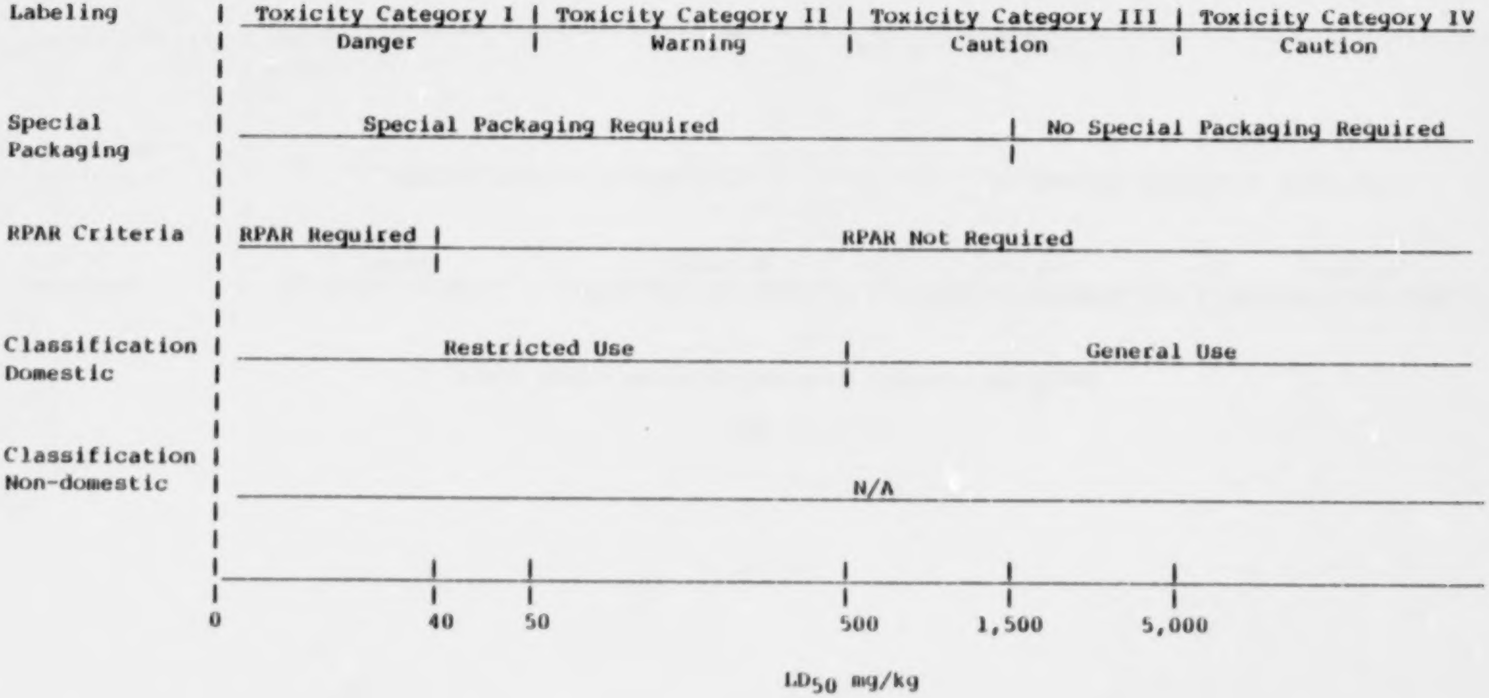
FIFRA HUMAN TOXICITY CRITERIA (INHALATION LC_{50})

Labeling	Toxicity Category I Danger		Toxicity Category II Warning	Toxicity Category III Caution	Toxicity Category IV Caution
Special Packaging	Special Packaging Required			No Special Packaging Required	
RPAR Criteria	RPAR Required	RPAR Not Required			
Classification Domestic	Restricted Use			General Use	
Classification Non-domestic	Restricted Use		General Use		
	0	.04	.2	2	20

LD_{50} mg/l

EXHIBIT 6-15

FIFRA HUMAN TOXICITY CRITERIA (ACUTE ORAL LD_{50})


Labeling
Toxicity Category I
Danger
Toxicity Category II
Warning
Toxicity Category III
Caution
Toxicity Category IV
Caution
Special Packaging
Special Packaging Required
No Special Packaging Required
RPAR Criteria
RPAR Required
RPAR Not Required
Classification Domestic
Restricted Use
General Use
Classification Non-domestic
N/A
0
40
50
500
1,500
5,000
LD_{50} mg/kg

APPENDIX A

PESTICIDE PRODUCTS CONTAINING THE ACTIVE INGREDIENTS LISTED BELOW HAVE BEEN CLASSIFIED FOR RESTRICTED USE FOR ONE OR MORE REGISTERED USES

Active Ingredient	Formulation	Criteria Influencing Restriction
Acrolein	As sole active ingredient. No mixtures registered.	Inhalation hazard to humans. Residue effects on avian species and aquatic organisms.
Acrylonitrile	In combination with carbon tetrachloride. No registrations.	Other hazards--accident history of both acrylonitril and carbon tetrachloride products.
Aldicarb	As sole active ingredient	Other hazards--accident history.
Allyl alcohol	All formulations	Acute dermal toxicity.
Aluminum phosphide	As sole active ingredient. No mixtures registered.	Inhalation hazard to humans.
Azinphos methyl	All liquids with a concentration greater than 13.5 percent.	Inhalation hazard to humans.
Calcium cyanide	As sole active ingredient. No mixture registered.	Inhalation hazard to humans.
Demeton	All granular formulations, emulsifiable concentrates and con-concentrated solutions.	Domestic uses: Acute oral toxicity. Acute dermal toxicity. Non-domestic outdoor uses. Residue effects on avian and mammalian species.

APPENDIX A
(Continued)

PESTICIDE PRODUCTS CONTAINING THE ACTIVE INGREDIENTS LISTED BELOW HAVE BEEN CLASSIFIED FOR RESTRICTED USE FOR ONE OR MORE REGISTERED USES

Active Ingredient	Formulation	Criteria Influencing Restriction
		Acute dermal toxicity. Residue effects on mammalian and avian species.
Endrin	All emulsions, dusts, wettable powders, pastes, and granular formulations.	Acute dermal toxicity. Hazard to nontarget organisms.
Ethyl parathion		Hazard to nontarget organisms. Inhalation hazard to humans. Acute dermal toxicity. Residue effects on mammalian, aquatic, avian species.
Fluoracetamide/1061	As sole active ingredient in baits. No mixtures registered.	Acute oral toxicity.
Hydrocyanic acid	As sole active ingredient. No mixtures registered.	Inhalation hazard to humans.
Methomyl	All granular formulations	Residue effects on mammalian species. Other hazards --accident history.

APPENDIX A
(Continued)

PESTICIDE PRODUCTS CONTAINING THE ACTIVE INGREDIENTS LISTED BELOW HAVE BEEN CLASSIFIED FOR RESTRICTED USE FOR ONE OR MORE REGISTERED USES

Active Ingredient	Formulation	Criteria Influencing Restriction
	In 1.24 percent to 2.5 percent dusts as sole active ingredient and in mixtures with fungicides and chlorinated hydrocarbon, inorganic phosphate and biological insecticides.	Same.
Methyl bromide	All formulations in containers greater than 1.5 lbs. Containers with not more than 1.5 lbs. of methyl bromide with 0.25 percent to 2.0 percent chloropicrin as an indicator. Container with not more than 1.5 lbs. having no indicator.	Same.
Methyl parathion	All formulations.	Other hazards--accident history. All foliar applications restricted based on residue effects on mammalian and avian species. Residue effects on avian species. Hazard to bees. Acute dermal toxicity. Residue effects on mamallian and avian species.
Mevinphos	all emulsifiable concentrates and liquid concentrates. 2 percent dusts.	Same. Acute dermal toxicity. Residue effects on mammalian and avian species.

APPENDIX A
(Continued)

PESTICIDE PRODUCTS CONTAINING THE ACTIVE INGREDIENTS LISTED BELOW HAVE BEEN CLASSIFIED FOR RESTRICTED USE FOR ONE OR MORE REGISTERED USES

Active Ingredient	Formulation	Criteria Influencing Restriction
Paraquat (dichloride) and paraquat bis(methyl sulfate)	All formulations and concentrations except those listed below. Pressurized spray formulations containing 0.44 percent Paraquat bis(methyl sulfate) and 15 percent petroleum distallates as active ingredients. Liquid fertilizers containing concentrations of 0.025 percent paraquat dichloride and 0.03 percent atrazine; 0.03 percent paraquat dichloride and 0.37 percent atrazine, 0.04 percent paraquat dichloride and 0.49 percent atrazine.	Other hazards. Use and accident history. Human toxicological data.
Picloram	All formulations and concentrations except tordon 101 R (forestry herbicide containing 5.4 percent picloram & 20.9 percent 2,4-D).	Hazard to nontarget organisms (specifically nontarget plants both crop and noncrop.

CLEAN AIR ACT--STATUTORY REVIEW

OVERVIEW OF THE ACT

The Clean Air Act (CAA) is a comprehensive attempt to address the nation's air pollution problems. The legislation was first enacted as the Clean Air Act of 1963. Significant amendments include the Clean Air Act of 1970 and the Clean Air Act Amendments of 1977. The CAA creates a series of programs through which the Environmental Protection Agency (EPA) is authorized to promulgate regulations to "protect and enhance the quality of the nation's air resources. . . ." (42 USC §7401).

The provisions for regulating air pollutants may be grouped into two classes: air quality standards and emission standards.

Sections 108-109 authorize EPA to determine the levels at which air pollutants can safely be tolerated in the atmosphere and to establish national ambient air quality standards (NAAQS). Control strategies ("implementation plans") for emissions sources are developed on a pollutant-by-pollutant and state-by-state basis. State plans must demonstrate that concentrations of regulated pollutants in each air quality control region will not exceed the national ambient air quality standards by the statutory deadlines.

Other sections of the CAA (i.e., 111, 112, 157, 202, 211, and 231) authorize EPA to control pollution at the source by establishing uniform national emission limits and standards. Among them are the New Source Performance Standards (NSPS), the Federal Mobile Source Emission Standards, National Emission Standards for Hazardous Air Pollutants, and the regulation of pollutants which may damage the ozone layer.

The following provisions of the Clean Air Act are examined in this statutory review:

- Section 108--Air Quality Criteria
- Section 109--National Ambient Air Quality Standards
- Section 110--State Implementation Plans
- Section 111--New Source Performance Standards
- Section 112--National Emission Standards for Hazardous Air Pollutants
- Section 122--Certain Unregulated Pollutants
- Section 157--Ozone Protection

- Section 202--Motor Vehicle Emissions
- Section 211--Regulation of Fuels
- Section 231--Aircraft Emissions

A summary at the end presents an overview of the statutory criteria and EPA's regulatory alternatives.

SECTIONS 108-109: NATIONAL AMBIENT AIR QUALITY STANDARDS (NAAQS)

The procedure for issuing National Ambient Air Quality Standards is outlined in the Clean Air Act. The three distinct stages of this procedure are:

(1) Listing air pollutants in the Federal Register;

(2) Issuing air quality criteria; and

(3) Proposing and promulgating primary and secondary ambient air quality standards.

Each of these stages is summarized below.

Listing. Section 108(a)(1) directs EPA to list each air pollutant:

> "(A) emissions of which, in [the Administrator's] judgment, cause or contribute to air pollution which may reasonably be anticipated to endanger public health or welfare;
>
> (B) the presence of which in the ambient air results from numerous or diverse mobile or stationary sources; and
>
> (C) for which air quality criteria had not been issued before the date of enactment of the Clean Air Amendments of 1970, but for which it plans to issue air quality criteria under this section."[1]

In general terms, the effects of pollutants on public health and public welfare and the number and diversity of sources emitting a particular air pollutant are the statutory criteria used by EPA to list substances under Section 108. The Second Circuit Court of Appeals has decided that if an air pollutant meets conditions (A) and (B), it must be listed by EPA under

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[1] 42 USC §7408 (emphasis added).

Section 108. The Court pointed to the statutory language and legislative history of the Clean Air Act as support for this position.[2]

Although criterion (B) is relatively objective, criterion (A) specifically requires an exercise of judgment based on a three-part test. To be listed emissions of a pollutant must:

(1) "cause of contribute to air pollution" which

(2) "may reasonably be anticipated" to

(3) "endanger public health".

Congress meant to require the EPA "to consider all sources of the contaminant which contribute to air pollution and to consider all sources of exposure to the contaminant--food, water, air, etc.--in determining health risk."[3]

The phrase "cause or contribute" authorizes listing of a substance even in the absence of definitive human or animal data which demonstrate a causal relationship between the polluting chemical and health effects. This allows the agency to make judgments about chemical substances based on suggestive epidemiological data or case reports.

The phrase "reasonably be anticipated" likewise requires less than complete certainty with respect to, for example, dose-response effects.

> In evaluating what "may reasonably be anticipated," the limitations and difficulties inherent in environmental medical research . . . must be considered.[4]

The phrase "endanger public health" has been the subject of litigation and Congress has explained its intent in using this phrase: "In order to emphasize the precautionary or preventive purpose of the [CAA] (and, therefore, the Administrator's duty to assess risks rather than wait for proof of actual harm), the committee not only retained the concept of endangerment to health; the committee also added the words "may reasonably be anticipated".[5]

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[2] Natural Resources Defense Council, Inc., et al. v. Russell Train, 411 F.Supp. 864 (S.D.N.Y., 1976), aff'd., 545 F.2d 320 (2d Cir., 1976). See also Indiana & Michigan Electric Co. v. EPA, 509 F.2d 839, 841 (dicta) (7th Cir. 1975); Kennecott Copper Corp. v. EPA, 462 F.2d 846, 857 (D.C. Cir. 1972) (dicta); but cf. St. Joe Minerals Corp. v. EPA, 508 F.2d 743, 744 n. 3 (3d Cir. 1975), vacated as moot, ____ U.S. _____; 48 L.Ed. 2d 812 (1976).

[3] H.R. Rpt. No. 95-294, p. 51, Legislative History of Clean Air Act Amendments of 1977, p. 2518. [Emphasis added.]

[4] Ibid.

These key phrases are used throughout the CAA and they are reviewed in more detail later.

Air Quality Criteria. Within 12 months after listing an air pollutant, the Clean Air Act instructs EPA to issue air quality criteria for the pollutant. Air quality criteria must, "accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air, in varying quantities".[6]

The Act suggests that the air quality criteria include information on:

> "(A) those variable factors (including atmospheric conditions) which of themselves and in combination with other factors may alter the effects on public health or welfare of such air pollutant;
>
> (B) the types of air pollutants which, when present in the atmosphere, may interact with such pollutant to produce an adverse effect on public health or welfare; and
>
> (C) any known or anticipated adverse effects on welfare".[7]

EPA may revise the criteria to include new scientific information at any time. The sole purpose of air quality criteria is to document the scientific basis for regulating a particular chemical under Section 109 of the Clean Air Act.

National Ambient Air Quality Standards. Section 109 of the statute requires EPA to propose regulations prescribing national primary and secondary ambient air quality standards (NAAQS) for each air pollutant for which air quality criteria have been issued. Primary ambient air quality standards are intended "to protect the public health," while secondary standards are intended to protect public welfare.

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[5] Ibid.

[6] Clean Air Act, Section 108(a)(2).

[7] Clean Air Act, Section 108(a)(2)(A-C).

NAAQS for each pollutant are proposed with the issuance of the criteria document and included in Title 40 of the Code of Federal Regulations as Part 50. Pollutants for which NAAQS have been promulgated are referred to as "criteria pollutants".

According to the statute, NAAQS must be based exclusively on air quality criteria issued by EPA for each air pollutant. The Act does not require EPA to consider costs of achieving the standards or the feasibility of implementing the standards. Moreover, the legislative history of the Clean Air Act firmly advises that such issues are "not germane" to the determination of NAAQS.[8] Recently the Court of Appeals for the District of Columbia ruled that the language and legislative history of Section 109 made it clear that economic and technological feasibility considerations are not to be factors in promulgating NAAQS.[9]

The level of protection which these standards must provide is stipulated in the CAA. Primary standards must be set conservatively, "allowing an adequate margin of safety" "requisite to protect the public health" from the effects documented in the air quality criteria. As one Court has stated: "It is irrelevant that the current state of scientific knowledge may make it difficult to set an ambient air quality standard. The [EPA] Administrator must proceed in spite of such difficulties."[10] The statute does not define the terms "adverse health effect" or "adequate margin of safety."

In establishing primary standards, EPA has not defined the term "adequate margin of safety" explicitly. In issuing the ozone standard for photochemical oxidants, the agency announced that the decision about what standard protects public health with an adequate margin of safety "is based on the uncertainty that any given level is low enough to prevent health effects, and on the relative acceptability of various degrees of uncertainty, given the seriousness of the effects."[11] The legislative history of the Act indicates that providing a margin of safety means primary ambient air standards must protect against hazards which research has not yet identified such as synergistic effects.[12]

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[8] A Legislative History of the Clean Air Act, 93rd Congress, 2nd Session, January 1974 (hereafter referred to as Legislative History) and 43 FR 26963 (June 22, 1978).

[9] Lead Industries Association v. EPA, 14 ERC 1906, --- F.2d --- (D.C. Cir. 1980), cert. den. 15 ERC 2097 (1980).

[10] NRDC v. Train, 545 F.2d 320, 324n.5 citing as support A Legislative History of the Clean Air Act Amendments of 1970, Vol. 1, p. 411 (1974).

[11] 44 FR 8215.

In the case of most air pollutants, there is no clear threshold for adverse health effects. This uncertainty necessitates the determination of an adequate margin of safety, and forces EPA to make assumptions and estimations after considering all available scientific evidence. In the past, primary standards have been set at more restrictive levels than those concentrations implicated in the criteria document as associated with adverse health effects; however, there is no general or consistent rule applied to all pollutants by which EPA determines an adequate margin of safety. See Exhibit 7-1.

The EPA's approach to setting a margin of safety for airborne lead also was litigated in Lead Industries Association, Inc., v. EPA. Each conservative assumption used in setting the standard was challenged as being a margin of safety and the cumulative effect was criticized as resulting in too stringent a standard. The court, however, rejected this characterization because some of EPA's decisions were questions of scientific judgment (not allowances for safety) and none of those decisions were arbitrary and capricious. Economic and technological feasibility considerations were also ruled not to be factors in establishing a margin of safety.[13]

The legislative history of the Clean Air Act indicates that EPA, when establishing primary standards, is to direct its efforts at groups of "particularly sensitive citizens such as bronchial asthmatics and emphysematics who in the course of daily activity are exposed to the ambient environment."[14]

The Court also held that Congress directed the EPA to protect against effects which "have not yet been uncovered by research and effects whose medical significance is a matter of disagreement." The Court found that the provision for an adequate margin of safety to "protect against unknown dangers supports this conclusion." The statutory provisions and legislative history convinced the Court that Congress wanted the EPA to err on the side of caution in making the necessary decisions. Thus, it rejected the argument that a standard need protect against only health effects that are "known to be clearly harmful."[15]

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[12] Legislative History, p. 410.

[13] Lead Industries Association, Inc. v. EPA, Ibid.

[14] Legislative History p. 410.

[15] Lead Industries Association, Inc. v. EPA, 14 ERC 1906, 1924 (D.C. Cir. 1980).

EXHIBIT 7-1

EFFECTS THRESHOLD, BEST CHOICE SIGNIFICANT RISK LEVELS AND SAFETY MARGINS CONTAINED IN PRIMARY AMBIENT AIR QUALITY STANDARDS

Pollutant	Lowest best judgment estimate for effects threshold and best choice for significant risk levels		Adverse health effect	U.S. primary air quality standard	Margin of safety* (percent)
	Concentration	Averaging time			
Sulfur dioxide	300 to 400 ug/m^3	24 hour	Mortality increase	365 ug/m^3	None
	91 ug/m^3	Annual	Increased frequency of acute respiratory disease	80 ug/m^3	14
Total suspended particulates	250 to 300 ug/m^3	24 hour	Mortality increase	260 ug/m^3	None
	70 to 250 ug/m^3	do.	Aggravation of respiratory disease	260 ug/m^3	None
	100 ug/m^3	Annual	Increased frequency of chronic bronchitis	75 ug/m^3	33
Suspended sulfates	10 ug/m^3	24 hour	Increased infections in asthmatics	None	None
	15 ug/m^3	Annual	Increased lower respiratory infections in children	None	None
Nitrogen dioxide	140 ug/m^3	do.	Increased severity of acute respiratory illness in children	100 ug/m^3	40
Carbon monoxide	23 ug/m^3	8 hour	Diminished exercise tolerance in heart patients	10 ug/m^3	**130
	73 ug/m^3	1 hour	Diminished exercise tolerance in heart patients	40 ug/m^3	**82
Photochemical oxidants	200 ug/m^3	do.	Increased susceptibility to infection	160 ug/m^3	25

* Safety margin equals effects threshold minus standard divided by standard X 100.

** Safety margins based upon carboxyhemoglobin levels would be 100 percent for the 8 hour standard and 67 percent for the 1 hour standard.

120 Cong. Rec. 18973 (1974) (report of Drs. Finklea, Hammer & Cole).

Likewise, the Court found that the mere fact that the pivotal health effects (i.e., blood lead elevation) relied upon in setting the lead standard are "subclinical"[16] does not detract from their significance for human health. The court held that these effects are a proper basis for setting air quality standards because of their relationship to more serious health effects particularly in children, who are very sensitive to lead exposures. The Court of Appeals case found that "the widespread presence of this toxic metal [lead] in the environment poses a significant health risk."

Thus, to develop primary standards EPA must:

(1) specify the significance (i.e., nature and severity) of the health effects;

(2) characterize the sensitive population;

(3) determine the probable adverse health effect level in sensitive persons; and

(4) estimate the level below the probable effect level which provides an adequate margin of safety to reduce or eliminate the risk.

Secondary standards must "protect the public welfare from any known or anticipated adverse effects" of a pollutant.[17] EPA has interpreted the requirements of Section 109 to mean that secondary national ambient air quality standards "are necessarily limited to demonstrable or predictable effects which can be quantitatively related to pollutant concentrations in the ambient air."[18] In the case of ozone, however, EPA did not have or require quantitative data relating the cause and welfare effect.[19]

The Agency also explicitly specifies that secondary standards be established to protect the public welfare from *adverse* effects, rather than from *all* effects.[20] As a result, welfare effects of a particular air pollutant revealed by quantitative data must further be shown to be adverse before secondary standards will be established based on them.

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[16] "Subclinical" effects can be detected only through laboratory tests and not through observation or physical examination.

[17] CAA §109(b)(1), (12); 42 USC §7409 (b)(1), (2).

[18] Preamble to the National Primary and Secondary Ambient Air Quality Standards for Sulfur Oxides, 38 FR 25679 (September 14, 1973).

[19] See 44 FR 8217 (February 8, 1979).

[20] *Ibid*.

Section 302(h) of the Act defines adverse public welfare effects as including, but not limited to, "effects on soils, water, crops, vegetation, man-made materials, animals, wildlife, weather, visibility, and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values and on personal comfort and well being". Because secondary standards are designed to protect welfare in addition to health, they are set at more restrictive levels than primary standards. Effects on economic values refers to the economic costs of pollution, not complicance costs.

There are no generic specifications in the statutory provisions for issuing short-term or long-term standards. EPA has promulgated both types of standards; the Agency interprets the Clean Air Act to require a short-term standard only if the scientific evidence presented in the criteria document warrants such protection.[21] The 1977 Amendments directed EPA to establish a three-hour standard for NO_2 concentrations unless there is no significant evidence that such a short-term standard is "requisite the protect the public health."[22]

SECTION 110: STATE IMPLEMENTATION PLANS (SIPs)

The intent of national primary and secondary ambient air quality standards is to control air pollutants with a broad national impact. By providing a minimum standard for air quality across the nation, NAAQS regulates chemicals emitted from widely distributed sources and present in the ambient air in all areas of the United States. It was Congress' intention that the states should play a large role in the implementation and enforcement of the NAAQS.[23] Each state is responsible for the submission of a state implementation plan (SIP) which describes the methods by which the individual state intends to meet the NAAQS in the air quality control regions within its jurisdiction. The states have latitude in the design of the SIPs, but each SIP must be approved by EPA. If necessary, EPA will develop a plan for a state. EPA cannot require a level of control technology that is technologically and economically infeasible.[24]

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[21] Ibid.

[22] CAA §109(c); 42 USC 7409(c).

[23] CAA Section 1, 42 USC §7401.

[24] Bunker Hill Co. v. EPA, 572 F.2d 1286 (9th Cir. 1977).

SIPs are the primary mechanisms through which NAAQS are to be achieved. Under the CAA, states may issue more stringent ambient air standards than the national standards. Additionally, states may establish ambient air quality standards for pollutants not included in the national standards. The states are not required to establish uniform emission limits for existing sources of criteria pollutants with the exception of certain volatile organic compounds subject to regulation under Control Technique Guidelines (CTGs). While states may consider economic and technological feasibility in selecting a mix of control devices, they must nevertheless develop a plan to meet the strict deadlines for attainment of the NAAQS. The primary standards are to be achieved first; secondary standards are to be achieved as soon as practicable after achievement of the primary standards. Moreover, in reviewing state implementation plans, the EPA may not consider economic or technological feasibility.[25]

In upholding the use of a particular air dispersion model for SO_2 emissions limits included in a SIP, the Sixth Circuit Court of Appeals noted that if the model did overpredict emission rates, "such a conservative approach in protection of health and life was apparently contemplated by Congress" in requiring that emission limits be established "to insure attainment and maintenance of national ambient air standards."[26]

SECTION 111: NEW SOURCE PERFORMANCE STANDARDS (NSPS)

To facilitate the achievement of NAAQS, EPA is authorized to set emissions standards for all newly constructed significant sources of pollution. Section 111(b)(1)(A) of the CAA instructs EPA to list all categories of stationary sources which are determined by the Agency to "cause or contribute significantly to air pollution which may reasonably be anticipated to endanger public health or welfare".[27] For each category cited, EPA must establish a uniform federal standard of performance to apply to all newly constructed or modified stationary sources.

The principal purpose of NSPS is to assure that over the long-term industrial development will not degrade the quality of the air. Additionally, these standards are intended to assure that new sources do not cause significant air pollution problems which prevent the attainment of National Ambient Air Quality Standards.[28]

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[25] See Union Electric v. EPA, 427 U.S. 246, 257-8, 265-266 (1976).

[26] Cleveland Electric Illuminating Co. v. EPA, 572 F.2d 1150 (6th Cir. 1970), cert. den. 439 U.S. 910 (1978).

[27] CAA Section 111; 42 USC §7411.

[28] A Legislative History of the Clean Air Act, p. 227. See also National Asphalt Paving Association v. Train, 539 F.2d 775 (D.C. Cir. 1976).

NSPS are functionally different from NAAQS in four ways. First, the definitions in the statute indicate that emissions limits of NSPS are more stringent than those that would exist under NAAQS. Standards of performance under NSPS must reflect the "best technological system of continuous emission reduction" which EPA determines "has been adequately demonstrated." To be adequately demonstrated, the pollution control technology must be available at a cost and at a time which EPA determines to be reasonable.

When establishing standards of performance, EPA must consider:

- the cost of achieving the emission reduction, and
- any non-air quality health, environmental, and energy impacts.[29]

Second, NSPS regulate emissions rather than overall air quality levels. Third, NSPS are directed towards specific types of pollution sources (i.e., categories of pollution sources which emit dangerous pollutants). The phrase "cause or contribute significantly to air pollution which may reasonably be anticipated to endanger public health or welfare" has the same meaning as in Section 109. Fourth, NSPS may also be design, equipment, work practice or operational standards. (See 111(h)).

Finally, Section 111(d) extends the treatment of new sources to existing sources, under certain circumstances. If an NSPS is issued for a substance not listed under Sections 108(a) or 112(b), EPA can require existing sources to meet comparable standards, taking "into consideration, among other factors, the remaining useful life of the existing source[s]" involved. The "other factors" are nowhere specified but would presumably include the factors required to be considered in establishing NSPS -- cost, non-air quality health and environmental impact, and energy requirements.

The health effects criteria for using standards under Section 111 are less stringent than those required for regulating hazardous air pollutants under Section 112, which will be discussed next. Similarly, Section 111 requires the consideration of costs and technological availability but neither of these considerations is mentioned in Section 112.

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[29] Although EPA must take costs into account, formal cost-benefit analysis is not required. See Portland Cement Association v. Train, 513 F.2d 506 (D.C. Cir. 1975), cert. den. 423 U.S. 1025; Portland Cement Association v. Ruckelshaus, 486 F.2d 375 (D.C. Cir. 1973), cert. den. 417 U.S. 921 (1974).

SECTION 112: NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS (NESHAPs)

A "hazardous air pollutant" is defined by Section 112 as "an air pollutant to which no ambient air quality standard is applicable and which in the judgment of the Administrator causes, or contributes to, air pollution which may reasonably be anticipated to result in an increase in mortality or an increase in serious irreversible, or incapacitating reversible illness".[30] The underlined terms have, by analogy, the same meaning as in Sections 109 and 111. Air pollutants qualifying as hazardous are not regulated by ambient air quality standards, but instead are subject to the special controls of Section 112. EPA is directed to list all such pollutants and to promulgate rules controlling or disallowing their emissions.

If such a pollutant is listed, an emissions standard is to be proposed within six months after listing the chemical. This standard must provide "an ample margin of safety to protect public health." National emission standards may apply to one particular stationary source of a pollutant or to several categories of sources. If an emission standard is "not feasible"[31] EPA is authorized to issue "a design, equipment, work practice, or operational standard, or combination thereof which is adequate to protect the public health with an ample margin of safety".

The Clean Air Act allots 30 days for public comment after an emission standard is proposed. Unless evidence is presented during the public comment period that indicates an emission standard is unwarranted, final regulations must be issued within 180 days.

SECTION 122: LISTING OF CERTAIN UNREGULATED POLLUTANTS

Section 122(a) of the CAA (added in 1977) directs EPA to study four unregulated pollutants: radioactive pollutants,[32] cadmium, arsenic, and polycyclic organic matter. If EPA determines that emissions of these pollutants into the ambient air "will cause, or contribute to, air pollution which may reasonably be anticipated to endanger public health"[33] then the Agency must control or prohibit their emissions under existing regulatory schemes, namely NAAQS, NESHAPs, and NSPS, or any combination of these actions. The regulatory review discusses the listing of radionuclides and arsenic as hazardous air pollutants.

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[30] CAA Section 112, 42 USC §7412, emphasis added.

[31] "Not feasible" means (1) a hazardous pollutant(s) "cannot be emitted through a conveyance designed and constructed to emit or capture such pollutant, or any requirement for, or use of, such a conveyance would be inconsistent with any federal, state or local law", or (2) "the application of measurement methodology to a particular class of sources is not practicable due to technological or economic limitations", (Clean Air Act, Section 112(e)(2), emphasis added).

[32] The term "radioactive pollutants" includes "source material, special nuclear material, and byproduct material" (42 USC §7422).

Congress specified the four pollutants to be studied and possibly regulated because EPA had failed to establish standards controlling the substances despite their "proven carcinogenicity".[34] Specific reasons for designating each pollutant to be studied are discussed below.

- Radioactive Pollutants. Congress was concerned about the well known hazards of radioactivity including increased risk of cancer, mutagenic effects, and genetic damage. Furthermore, the accumulating evidence of new emission sources and documented effects of low-level ionizing radiation were instrumental in Congress' listing of radioactive pollutants for study.[35]

  The House Committee on Interstate and Foreign Commerce recommended that, considering the number of unknown sources and uncertain aspects of radioactive wastes and waste management, EPA should trace and control those increments of radioactive pollutants which can be identified.[36] This meant a shift in responsibility from the Nuclear Regulatory Commission to the EPA.[17]

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[33] CAA Section 122, 42 USC §7422.

[34] House Report No. 95-294, Committee on Interstate and Foreign Commerce, p. 36.

[35] Two major sources were cited as being instrumental in Congress' addition of radioactive pollutants: (1) Proceedings of a Congressional Seminar on Low-Level Ionizing Radiation (November 1976); and (2) Mason Willrich, (Radioactive Waste Management and Regulation, U.S. Energy Research and Development Administration, MIT Energy Laboratory, September 1, 1975.

[36] The primary radioactive sources cited for study were mine tailings, direct emissions from nuclear powerplants and nuclear energy research facilities, evaporation of radioactive waste from water discharges, nuclear weapon testing, and combustion of coal with a high radioactivity content. House Report, No. 95-294, p. 43.

- Cadmium. Congress cited two studies which demonstrated the health risks of occupational and nonoccupatonal exposure to cadmium emissions as the primary reason for listing cadmium in Section 122 of the CAA. One study, Man, Materials, and Environment: A Report to the National Commission on Materials Policy (National Academy of Sciences, March 1973), implicated cadmium in the cause of cardiovascular disease, respiratory disease, and cancer. Another study by the University of Tennessee, Oak Ridge in 1975 showed that cadmium concentrates in biological systems with symptoms not appearing for 10 to 20 years. Thus, Congress decided that closer study and possible regulation of cadmium was necessary.

- Arsenic. This element has long been known as a toxic material with cancer potential. Several studies in 1975 and 1976[18] indicated that people living near copper smelters and arsenical pesticide plants had high levels of arsenic in their tissues and urine. For these reasons, Congress labeled arsenic as a possible candidate for regulation under the Clean Air Act and listed it in Section 122.

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[17] The House Committee cited four reasons for changing the primary responsibility for radioactive air emissions from the Nuclear Regulatory Commission (NRC) to EPA. First, the Committee felt there was no reason to exempt certain pollutants from the comprehensive provisions of the Clean Air Act. Second, NRC's authority to regulate radioactive air pollutants was not broad enough to protect public health. NRC regulated air pollutants from nuclear facilities, but was not authorized to control radioactive air pollutants from nonnuclear sources, or from certain Defense Department facilities. Including radioactive pollutants under the Clean Air Act covered these gaps in authority. Third, NRC was primarily concerned with nuclear plant siting and construction, not environmental considerations. Congress decided that EPA, with NRC consultation, was the most qualified agency to deal with radioactive sources. Fourth, the committee hoped to eliminate any duplication of effort by EPA and NRC. House Report No. 95-294, p. 43.

[18] These studies included, (1) NAS-EPA Report, Arsenic, November 1976; (2) A National Cancer Institute Study of Copper Smelters, 1975; and (3) A Johns Hopkins University study of neighborhood located near a pesticide plant.

- Polycyclic Organic Matter (POM). Testimony by several experts at the committee hearings on the Clean Air Act Amendments and recommendations from the National Air Quality Commission led to the addition of POMs to the list of "unregulated pollutants". The testimony and recommendations were based on an EPA Report[39] and a NAS Report[40] which showed POMs to be associated with lung and skin cancer in humans and animals.

SECTIONS 153, 154, 155 AND 157: OZONE PROTECTION

The CAA Ozone Protection provisions are twofold:

(1) Sections 153, 154, and 155 direct EPA to conduct studies on halocarbon emissions and other substances[41] which "affect the ozone in the stratosphere" and "may cause or contribute to harmful effects on public health or welfare".

(2) Section 157 authorizes EPA to promulgate regulations to control "any substance, practice, process, or activity (or any combination thereof) which . . . may reasonably be anticipated to affect the stratosphere, especially ozone in the stratosphere, if such effect in the stratosphere may reasonably be anticipated to endanger public health or welfare," (emphasis added).

Congress included both sections in the 1977 Amendments to the CAA because of possible affects of halocarbons and other pollutants on human health. Halocarbons were used as propellants in aerosol spray cans and refrigerators, and were postulated to deplete the ozone layer (in the stratosphere) which screens out the majority of ultraviolet radiation reaching the earth. The postulated long-term (10 or 20 years) human health effects from an increase in ultraviolet radiation were an increased rate of human skin cancer.[42] Congress decided that, although the facts on ozone depletion were not conclusive, the time lag involved dictated that regulation might be necessary to safeguard the public health.[43]

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[39] Scientific and Technical Assessment Report on Polycyclic Organic Matter, EPA, March 1975.

[40] Particulate Polycyclic Organic Matter, NAS, 1972.

[41] Section 153 specifically requires studies of the effects of halocarbons, chlorine, bromine compounds, and aircraft emissions on the stratosphere (42 USC §7453).

[42] House Report No. 94-575, p. 94.

The statute does not mandate immediate regulation, but rather charters studies to provide information on the need for future action. If regulation is necessary, Section 157(b) instructs EPA to "take into account" the feasibility and the costs of regulation. Additionally, medical use products may be exempted from regulations if there is "no suitable substitute".

It is important to note that EPA's authority to control halocarbons and other substances that might deplete the ozone layer does not restrict EPA's authority under TCSA, or the authority of FDA, CPSC or other agencies to act under other laws to regulate these substances.[44]

Section 202: Motor Vehicle Emissions Standards

The purpose of Section 202, Motor Vehicle Emission Standards, is to achieve a level of air quality which meets the National Ambient Air Quality Standards. Congress cited data revealing that in 1968, moving sources were responsible for more than 42 percent of the total emissions of the five major pollutants.[45] In order to meet the National Ambient Air Quality Standards, Congress determined that significant reductions in the emissions from automobiles were necessary.[46] Congress identified carbon monoxide, hydrocarbons, nitrogen oxides, and particulates as substances contained in automobile emissions and contributing to poor air quality. In fact, available evidence demonstrated that automobiles were emitting 64 percent of the carbon monoxide and 50 percent of the hydrocarbons in the ambient air. This led to the inclusion of emission standards in Section 202 of the Clean Air Act for these four substances: Carbon monoxide, hydrocarbons, nitrogen oxides, and particulates.[47]

Section 202(a)(3)(A) requires EPA to establish emission standards for carbon monoxide, hydrocarbons, and oxides of nitrogen for heavy-duty vehicles and engines, while Section 202(b)(1) requires emission standards for these chemicals from light-duty vehicles and engines. Furthermore, Section

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[43] House Report No. 95-294, pp. 95-99.

[44] House Conference Report, No. 95-564, p. 148.

[45] A Legislative History of the Clean Air Amendments of 1970, Senate Consideration of the Clean Air Act, December 1970, p. 126.

[46] *Ibid*.

[47] Discussions with the Mobile Sources Division, EPA.

202(a)(3)(A)(iii) instructs EPA to prescribe regulations for *particulate matter* emissions from "classes or categories of vehicles manufactured during and after model year 1981" (42 USC 7521).

Section 202(a)(1) of the Clean Air Act gives EPA broad authority to identify and regulate substances emitted from motor vehicles which pose health or welfare risks. This provision instructs EPA to establish emission standards for *"any air pollutant* from any class or classes of new motor vehicles or new motor vehicle engines, which . . . may reasonably be anticipated to *endanger public health or welfare*" (emphasis added). EPA has not employed this broad authority, thus far, except with respect to nonexhaust hydrocarbon emissions.

Technological feasibility and economic costs need not be factors in setting standards under Section 202(a). Rather, Congress' intent was that standards "should be a function of the degree of control required, not the degree of technology available today".[48] Nevertheless, in establishing an implementation date, EPA must allow time "to permit the development . . . of the requisite technology, giving appropriate consideration to the cost of compliance. . . ."

Thus, this section authorized technology-forcing standards[49] while requiring that cost and technology be considered in setting a date for compliance. Consequently, EPA has taken technology and cost into account in setting standards under 202(a).[50]

SECTION 211: REGULATION OF FUELS AND FUEL ADDITIVES

Section 211 of the Clean Air Act authorizes EPA to set requirements for fuels and fuel additives to be used in mobile sources.[51] These requirements are twofold: First, EPA may require *any* fuel or fuel additive to be registered with EPA prior to selling, offering for sale or introducing into commerce that substance.[52] Second, EPA "may control or prohibit the manufacture, introduction into commerce, offering for sale or sale" of fuels and additives if their emission products (1) cause, or contribute to, "air pollution which may reasonably be anticipated to endanger the public health or welfare," or (2) "will impair to a significant degree the performance of any emission control device or system".

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[48] Senate Report No. 1196, 91st Cong., 2d Sess., p. 24 (1970).

[49] See Senate Report No. 127, 95th Cong., 1st Sess., p. 75 (1977) ("The Secretary is expected to press for the development and application of improved technology rather than be limited by that which exists.")

[50] See, e.g., 43 FR 37970 (1978) (evaporative emissions from light-duty trucks).

[51] Engine oil additives cannot be regulated under Section 211. *Lubrizol Corp. v. EPA*, 562 F.2d 807 (D.C. Cir., 1977).

[52] By January 1977, 1,920 fuel additives, 511 gasolines, and 250 diesel fuels had been registered. H.R. Rep. No. 294, 95th Cong., 1st. Sess. 307.

When a fuel or additive is registered, EPA may require manufacturers to submit various information including the effects of emission products on public health and public welfare, as well as the impact on the performance of emission control devices/systems (to the extent such information is known to the additive manufacturer). EPA also may require manufacturers "to conduct tests to determine potential public health effects of such fuel or additive (including, but not limited to, carcinogenic, teratogenic, or mutagenic effects)". In this way, EPA can monitor the composition of fuels and fuel additives to guard against the introduction of fuels or additives which could result in exhaust products damaging to public health, public welfare, and/or emission control devices.

Congress authorized EPA to regulate fuels and fuel additives because of concern about the direct and indirect hazards posed by fuel composition. The emission products of fuels and additives might pass through vehicles and directly endanger the public. Also, fuel additives might adversely affect devices for controlling other automotive emissions.[53] Thus, Section 211(c) authorizes EPA action on two alternative grounds. Exhibit 7-2 schematically illustrates the statutory criteria for regulating fuels and fuel additives. The two basic criteria are included, (1) endangering public health, and (2) impairing the performance of an emission control system. In the exhibit, the letters (e.g., (a), (b), . . .) indicate the factors EPA must consider in order to base regulations on the numbered criterion situated above.

Before regulations are prescribed based on the first criterion, EPA is required by Section 211(c)(2)(A) to consider "all relevant medical and scientific evidence available, including consideration of other technologically or economically feasible means of achieving emission standards under Section 202".[54]

To regulate fuels and fuel additives because they impair the performance of emission control devices, EPA must consider "available scientific and economic data, including a cost-benefit analysis comparing emission control devices or systems".[55]

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[53] Senate Report No. 1196, 91st Cong., 2d Sess., pp. 33-34 (1970).

[54] 42 USC §7545(c)(2)(A).

[55] Section 211(c)(2)(B); 42 USC §7545 (c)(2)(B).

EXHIBIT 7-2

STATUTORY CRITERIA FOR REGULATING FUELS AND FUEL ADDITIVES

Criterion (1)

Endangers Public Health

- (a) All relevant Medical and Scientific Evidence
- (b) Other Technologically or Economically Feasible Means
- (c) Fuel and Additive Substitutions

40 CFR 80

Criterion (2)
Impairs Performance of
Emission Control System

- (a) Available Scientific and Economic Data (Cost-Benefit Analysis)
- (b) Fuel and Additive Substitutions

40 CFR 80

In order to regulate a fuel or additive based on either criterion, EPA must publish evidence that prohibiting the use of the fuel or additive will not result in substitutions of other fuels or additives which prove harmful to public health "to the same or greater degree" than the use of the prohibited substance.[56]

Section 211(f) specifically limits the allowable concentration of manganese to .0625 grams for gallon and outlaws as well all other new fuels or additives which are not substantially similar to those already utilized. Likewise, 211(f) bans the increase in concentrations of existing additives. This section was added in 1977 because the Senate Committee was disturbed by reports that an organo-manganese additive called MMT impaired the performance of emission control devices for hydrocabons.[57]

Section 211 regulations have resulted in much litigation including three key cases:

(1) NRDC v. Train which established that fuel controls were intended by Congress as a means for attaining primary air quality standards rather than as an alternative to promulgating such standards.[58]

(2) Ethyl Corp. v. EPA which interpreted the risk of harm standard "will endanger" as precautionary in nature and not requiring proof of actual harm before regulating. This case held that §211 authorizes the EPA to assess risks of harm and, where risk is found to be significant, to act to prevent harm from happening.[59]

(3) Amoco Oil v. EPA which upheld regulations requiring "lead-free" fuel to protect emisson control systems. The opinion noted that the statute does not require that compliance be feasible or economically reasonable, but it does not preclude consideration of these factors.[60]

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[56] CAA Section 211(c)(2)(C); 42 USC §7545(c)(2)(B).

[57] Senate Report No. 127, 95th Cong., 1st Sess., p. 50 (1977).

[58] NRDC v. Train, 545 F.2d 320 (2d Cir., 1976).

[59] Ethyl Corp. v. EPA, 506 F.2d 1321 (D.C. Cir. 1975), rev'd. on reh. en banc 541 F.2d 1 (D.C. Cir. 1976), cert. den. 426 US 941 (1976).

[60] Amoco Oil v. EPA, 501 F.2d 722,741-3 (D.C. Cir., 1974).

These cases were decided before the 1977 Amendments to the Clean Air Act. The 1977 Amendments endorsed the Ethyl approach for the entire CAA as discussed elsewhere.[61]

SECTION 231: AIRCRAFT EMISSIONS

The statutory instructions for regulating aircraft emissions, Section 231, are identical to those for motor vehicle emissions. Section 231(a)(2) authorizes EPA to issue an aircraft emission standard for "any air pollutant from any class or classes of aircraft or aircraft engines which . . . causes, or contributes to, air pollution which may reasonably be anticipated to endanger public health or welfare" (42 USC 7571). Furthermore, the purpose of aircraft emission standards is the same as the purpose for motor vehicle emission standards: To achieve a level of air quality which meets NAAQS. Unlike the motor vehicle emission section of the Clean Air Act, Section 231 does not specify the substances to be regulated.[62] Section 231 also directs EPA to study aircraft emissions to determine the magnitude of the pollutant problem and the technological feasibility of controlling aircraft emissions. Regulations are to take effect after a period of time needed to develop the appropriate technology and giving appropriate consideration to the cost of compliance.

OVERVIEW OF STATUTORY AUTHORITY

Based on the foregoing review of the statutory provisions, legislative history, and caselaw, it is possible to draw some conclusions about EPA's authority to designate and regulate under the Clean Air Act. Exhibit 7-3 displays the key statutory criteria and terms. This Exhibit reveals overlaps and complementarities among the provisions as well as the bases for regulation. Some provisions are source-specific (e.g., new source standards, mobile source standards), others are more general. The role of economics and technological feasibility varies too. Most provisions are oriented toward achieving the NAAQS criteria pollutants but others are broader in scope. How the agency has used its CAA authority is discussed in the regulatory review. The following sections consider: (1) specificity in designating chemical

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[61] The Ethyl litigation focused exclusively on the question whether any regulation of fuel lead was justified by health considerations but did not address the specific ceiling on lead content chosen nor how this decision was reached.

[62] The same chemicals are regulated by aircraft emission standards as are regulated by motor vehicle emission standards with one exception. Hydrocarbons, carbon monoxide, and oxides of nitrogen are common to both standards while particulate matter is regulated only under Section 202, and smoke is regulated only under Section 231.

EXHIBIT 7-3

OVERVIEW OF CLEAN AIR ACT REGULATORY AUTHORITY

Section	Type of Regulation Authorized	Substances Regulated	Kind of Harm To Be Avoided	Certainty of Causality	Standards Based on	Cost and Technical Feasibility Factors?
109	Ambient Air Quality Standards	Pollutants from numerous or diverse mobile or stationary sources which cause or contribute to air pollution	Endangerment of public health Known or anticipated adverse welfare effects	May reasonably be anticipated to endanger public health or welfare	Health Effects Criteria Adequate margin of safety Welfare Effects Criteria	Not to be considered
111	Standards of Performance for New Sources (Emission Limits)	Pollutants from new stationary sources which cause or contribute significantly to air pollution	Endangerment of public health or welfare	May reasonably be anticipated to endanger public health or welfare	Technology Economic Cost Non air-quality health, environmental, and energy impacts	Best system of continuous emission reduction adequately demonstrated Must consider cost of achieving the emission reduction
112	National Emission Standards	Hazardous air pollutants from stationary sources which causes or contribute to air pollution	Increase in mortality or an increase in serious irreversible or incapacitating reversible illness	May reasonably be anticipated to result in an increase in mortality . . .	Ample margin for safety	Considered administratively, particularly for non-threshold carcinogens
157	Ozone Protection	Any substance, practice, process, or activity (or any combination thereof)	Endangerment of public health or welfare Effects on the stratosphere, especially ozone	May reasonably be anticipated to affect the stratosphere or endanger public health or welfare	Feasibility Costs Substitutes for medical products	EPA "shall" take into account the feasibility and the costs of achieving control

EXHIBIT 7-3
(continued)

OVERVIEW OF CLEAN AIR ACT REGULATORY AUTHORITY

Section	Type of Regulation Authorized	Substances Regulated	Kind of Harm To Be Avoided	Certainty of Causality	Standards Based on	Cost and Technical Feasibility Factors?
202(a)(1)	Motor Vehicle Emission Standards	Any pollutants from any class of new motor vehicles or motor vehicle engines which cause or contribute to air pollution	Endangerment of public health or welfare	May reasonably be anticipated to endanger public health or welfare	Need for Control	Must be factors in setting implementation date(s), but not for control standards
211	Control or prohibition of the manufacture, introduction into commerce, or sale of fuels and fuel additives	Fuels and fuel additives used in motor vehicles or motor vehicle engines	Air pollution which endangers public health or welfare Impairment to a significant degree of the performance of an emission control device or system	Emission products must cause or contribute to air pollution which may reasonably be anticipated to endanger the public health or welfare or Will impair to a significant degree emission control devices	Medical and Scientific Criteria Other technologically or economically feasible means Fuel and additive substitutions Economic data (cost-benefit analysis)	Technical feasibility considered in relation to regulations under Section 202. Economic feasibility considered only for regulation to avoid impairment of an emission control device or system
231	Aircraft Emission Standards	Pollutants from any class or classes of aircraft engines which cause or contribute to air pollution	Endangerment of public health or welfare	May reasonably be anticipated to endanger public health or welfare	Technology Cost of compliance	Standards must permit the development and application of the requisite technology Costs of compliance must be given appropriate consideration

substances; (2) designation criteria: harm, causality, and certainty; and (3) regulatory flexibility under the CAA.

Specificity in Designating Chemical Substances

A key issue in the regulation of toxic substances relates to the specificity with which chemical substances must be designated for regulation. The Clean Air Act seems to authorize the generic designation of related substances and EPA's regulations are written accordingly. The CAA defines "air pollutant" in an expansive manner as:

> any air pollution agent or combination of such agents, including any physical, chemical, biological, radioactive . . . substance or matter which is emitted into or otherwise enters the ambient air.[63]

Thus, the ambient air standard for particulate matter includes any substance that can be detected in that form. Although evidence is mounting that the most hazardous particulates are the smaller "respirable" ones, this relates to the size of the particles and not their chemical composition.

The definition of "air pollutant" underlies the NAAQS as well as the statutory authority for New Source Performance Standards and for mobile source standards. Hazardous air pollutants are simply "air pollutants" which have certain hazardous health effects (CAA Section 112). Throughout the Clean Air Act, Congress has relied on "generic" categories of pollutants and has, for example, directed EPA to study the desirability of regulating "radioactive pollutants" and "polycyclic organic matter" (CAA Section 122). Likewise, Congress requires the EPA to submit progress reports with respect to the control of sources of "halocarbon emissions" which are defined as:

> the chemical compounds $CFCl_3$ and CF_2Cl_2 and such other halogenated compounds as . . . may reasonably be anticipated to contribute to reductions in the concentration of ozone in the stratosphere.[64]

Only two legal cases have ruled on EPA's authority to regulate related substances under the CAA. In the case of airborne lead, EPA's inclusion of alleged insoluble and nonrespirable particles in the ambient air standards was upheld in court because there was some evidence of health effects from such particles.[65] In Ford Motor Company v. EPA, the EPA's regulation of automotive hydrocarbon emissions was challenged because the standard applied to both methane and nonmethane hydrocarbons. Methane is a nonreactive hydrocarbon which does not contribute to air pollution and EPA's NAAQS are specified in terms of nonmethane hydrocarbons.[66] Ford Motor Company argued that Section 202 does not permit EPA to control methane emissions because they do not "cause or contribute to air pollution which may reasonably be anticipated to endanger public health or welfare". The District of Columbia Court of Appeals upheld the EPA standard finding that (1) Congress used the term "hydrocarbons," (2) EPA's total hydrocarbon standard results in less emissions of harmful nonmethane hydrocarbons, (3) EPA's original pre-1970 standard was for total hydrocarbons and Congress ratified this approach in 1970 and 1977 implicitly. Finally, the Court pointed out that EPA need not regulate hydrocarbons according to the criteria of Section 202(a) but can rely on 202(b) instead, thus eliminating the need to demonstrate health effects.

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[63] CAA Section 302, 42 USC §7602(g).

[64] CAA Section 152, 42 USC §7452.

[65] Lead Industries Assoc., Inc. v. EPA, 14 ERC 1680, ___ F.2d ___ (D.C. Cir. 1980), cert. den. _____ U.S. _____ (1980).

Designation Criteria: Causality, and Certainty of Harm

In the 1977 Amendments to the Clean Air Act, Congress paid particular attention to the criteria required to regulate a substance under the CAA. The Congress moved to unify the disparate requirements of the 1970 Act by adopting a standardized basis for rulemaking under Sections 108 (criteria for national ambient air quality standards), 111 (new source standards of performance), 112 (hazardous emission standards, although the nature of the risk must be more serious), 202 (new motor vehicle standards), 211 (fuels and fuel additives, and 231 (aircraft emissions standards). EPA may now regulate a pollutant's emissions

> which in the judgment of the [EPA] Administrator cause or contribute to air pollution which may reasonably be anticipated to endanger public health or welfare.

The Congress had several goals in mind in adopting this formulation. The term "in the judgment of the [EPA] Administrator" was intended to modify both the "cause or contribute to" phrase and the "may reasonably be anticipated" phrase in order to emphasize the "necessarily judgmental element in the task of predicting future health risks of present action and to confer . . . the requisite authority to exercise such judgment". In order to emphasize "the precautionary or preventive purpose" of the Clean Air Act and the EPA's "duty to assess risks rather than wait for proof of actual harm" Congress retained from the 1970 Act the concept of endangerment to health and added the words "may reasonably be anticipated". By using the words "cause or contribute to air pollution," Congress intended the EPA to consider "all sources of the contaminant which contribute to air pollution and to consider all sources of exposure to the contaminant--food, water, air, etc.--in determining health risk".[67] This last point needs some clarification; in the case of lead,

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[66] See 44 FR 20086 (1979) (methane is photochemically unreactive and does not contribute to the formation of smog). Ford Motor Company v. EPA, 604 F.2d 685 (D.C. Cir., 1979) (per curiam).

> While [sic] the incremental effect of lead emissions on the total body lead burden is of no practical value in determining whether health is endangered, (1) the contribution must be significant before regulation is proper and (2) the incremental effect is of value in deciding whether the lead exposure problem can fruitfully be attacked through control of lead additives.[68]

Congress was motivated to clarify the EPA's regulatory authority following the decisions in the Ethyl case.[69] Among the issues raised in that case and answered in the 1977 Amendments are:

(1) The EPA may act to prevent harm before it occurs and need not find that actual harm has already occurred before it regulates.

(2) EPA's duty includes the assessment of risks and not just findings of past fact.

(3) EPA is not required to prove endangerment is caused by emissions of a pollutant from a single class of sources without respect to other sources of the pollutant; the EPA should consider the cumulative risk to public health from multiple sources of the pollutant, including total body burden resulting from all exposures.

(4) The same standard of proof should apply to regulation of mobile sources, fuels and additives, and stationary souces of emissions.

(5) Protection of public health should extend to susceptible individuals and not be limited to protection only of healthy adults.

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[67] Legislative History of the Clean Air Act Amendments of 1977, p. 1129.

[68] Ethyl Corp. v. EPA 541 F.2d 1,31n.62, citing 39 FR 33734.

[69] Ethyl Corp. v. EPA, 506 F.2d 1321 (D.C. Cir. 1976), cert. den. 426 U.S. 941. The Ethyl litigation concerned Section 211 regulation of additives but applied, through dicta, to the entire Clean Air Act.

(6) The court's standard of review should be whether the EPA has reached reasonable conclusions which are rationally justified.[70]

Practical constraints led the Congress to endorse and adopt these positions. Moreover, Congress felt it was moving in a direction consistent with most judicial interpretations of the CAA.[71] In light of the problems involved in regulating environmental contaminants, Congress clearly authorized the exercise of reasoned judgment and discretion in finding a middle road.

Summary of Regulatory Alternatives

The Clean Air Act presents the EPA with several statutory provisions which can be used to control air pollutants. Nevertheless, these provisions do not necessarily provide alternative remedies for regulating specific pollutants. One court has pointed out that "there is no language anywhere in the statute which indicates that the EPA has discretion to choose among the remedies" which the CAA provides.[72] The Second Circuit Court of Appeals likewise rejected EPA's argument that it could choose to control lead (or other pollutants) under Section 211 instead of listing it under Section 108 for the development of air quality standards.[73] The Court reviewed the legislative history of the 1970 CAA Amendments and concluded that both the Section 211 fuel controls and the Section 111 new source performance standards were intended by Congress as means for attaining ambient air quality standards rather than as alternatives to promulgating such standards.[74]

Thus, the existing caselaw suggests that the emission source controls authorized by §§109, 111, 202, 211, and 231 are supplements to air quality standards, not alternatives. Hazardous air pollutants are distinct because no air quality standard is supposed to be applicable to such pollutants by the express statutory language of Section 112; however, NESHAPs may be established for both new and existing sources, although not for mobile sources.

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[70] Legislative History, pp. 1126-28.

[71] Ibid., p. 1129, citing South Terminal Corp. v. EPA, 504 F.2d 646 (1st Cir., 1974); Amoco Oil v. EPA, 501 F.2d 722 (D.C. Cir., 1974); Texas v. EPA, 499 F.2d 289 (5th Cir., 1974); Portland Cement Assoc. v. Ruckelshaus, 486 F.2d 375 (D.C. Cir., 1973).

[72] NRDC v. Train, 411 F.Supp. 864,868 (S.D.N.Y., 1976).

[73] NRDC v. Train, 545 F.2d 320,324 (2d Cir., 1976).

[74] Ibid. at 325,326,327.

This state of affairs was altered by the 1977 Amendments to the Clean Air Act for certain specifically designated substances: radioactive pollutants, cadmium, arsenic, and polycyclic matter. Section 122 authorizes EPA to regulate emissions under the NAAQS, NSPS, or NESHAPs programs, or any combination of these actions. This does not seem, however, to overrule the holdings discussed above or the express language of Section 112.

For purposes of this review, a key issue is the regulation of substances under the NAAQS, NSPS, or NESHAPs programs. Exhibit 7-4 summarizes the differences between regulating chemicals under Section 109, Section 111, and Section 112 of the Clean Air Act.

First, the purposes are different. NAAQS's purpose is to provide a minimum standard for ambient air quality across the nation. Specific emission limits for sources must be developed by states and need not be uniform. NSPS and NESHAPs provide uniform emission standards for specific facilities that emit pollutants determined to be hazardous.

Second, the focus of NAAQS is on chemicals with a broad national impact. NAAQS is applicable to chemicals emitted from widely distributed stationary and mobile sources, and to chemicals generally present in the ambient air in all areas of the nation. The expressed legislative focus of Section 112 is on a specific class of chemical pollutants believed to be highly hazardous."[75] For example, because vinyl chloride emissions are a localized problem, they are regulated under Section 112, not Section 109.[76] The focus of Section 111 is on categories of sources and allows EPA to control a variety of pollutants emitted by specific industries.

Third, the factors to be considered and the level of protection afforded differs for each provision. Neither cost nor technology is to be considered in issuing NAAQS, both are to be considered as the basis for NSPS, and both have been considered in issuing NESHAPs, although Section 112 is silent about the role of these considerations. Furthermore, both Sections 109 and 112 require that standards provide a margin of safety; no similar requirement is included in Section 111.

Fourth, the National Ambient Air Quality Standards/State Implementation Plan process does not provide the expedited means of control that Section 111 or 112 regulation does. Under the NAAQS program, each state has discretion in developing a set of emission limits for stationary sources and also is given a

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[75] Taken from comments by congresspersons during House consideration of the Conference Committee Report on the NESHAP section. A Legislative History of the Clean Air Amendments of 1970, p. 116.

[76] See 40 FR 59534 (December 24, 1975).

EXHIBIT 7-4

SECTIONS 109, 111, AND 112 CONTRASTED

	Section 109 NAAQS	Section 111 NSPS	Section 112 NESHAP
Pollutants Covered	Any air pollutants	Any air pollutants	Hazardous Air Pollutants
Sources Covered	Numerous or diverse mobile or stationary sources	New stationary sources and existing stationary sources (111(d))	New or existing stationary sources
Health Criteria and Certainty/ Causality	May reasonably be anticipated to endanger public health or welfare	May reasonably be anticipated to endanger public health or welfare	May reasonably be anticipated to result in an increase in mortality or in serious irreversible or incapcitating reversible illness.
Type of Standard	National Ambient Air Quality Standard	Nationally uniform emission standards	Nationally uniform emission standards
Level of Protection	Adequate margin of safety	Not specified	Ample margin of safety
Required Considerations	Health Effects Criteria	Technology Cost Other Impacts	Not specified

lengthy time period to meet NAAQS standards. Theoretically, hazardous air pollutants may be regulated as Section 109 pollutants such as volatile organic compounds and particulates. However, EPA does not place special emphasis on the control of hazardous pollutants when approving State plans to implement Section 109. EPA approval of state implementation plans adds time to the regulatory process, too. If an air pollutant is toxic or carcinogenic, regulation under NSPS or NESHAPS may be more appropriate than regulation under NAAQS. Under both Section 111 and Section 112, the EPA has the authority to establish and enforce emission standards for both new and existing sources. Thus, Section 112 offers a faster regulatory process than Section 109. This time factor could be important in some cases for the protection of public health. Section 111 provides an expedited process, but only for new sources; control of existing sources under 111(d) must be implemented through the SIP process.

Finally, regulations under Section 109 or 111 are applicable to pollutants which endanger public health and public welfare, while regulations under Section 112 are applicable only to pollutants which seriously endanger public health.

Two Examples

Mercury v. Lead. Mercury and lead share many characteristics. These common characteristics include:

- adverse health effects result from exposure;
- multiple sources of exposure exist (air, drinking water, food);
- direct (inhalation) and indirect (ingestion) human exposure occurs;
- both chemicals accumulate in the human body;
- "safe" ambient concentration levels have been determined by EPA.

To be listed under Sections 108 and 109, the presence of the air pollutant in the ambient air must result from "numerous or diverse mobile or stationary sources."[77] Lead is emitted to the atmosphere by vehicles burning leaded fuel and by many stationary sources; thus, lead meets the legislative requirements of Sections 108 and 109. Sections 111 and 112 apply to stationary sources only, so regulation for air lead is more appropriate under NAAQS.

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[77] Clean Air Act. Section 108(a)(1)(B). Air Quality Criteria and Control Techniques. Emphasis added.

At first glance, mercury seems to fulfill the legislative requirements of Sections 108 and 109. Humans are exposed to multiple sources, i.e., airborne, waterborne, and foodborne, of mercury. Unlike lead, there are only two major sources of mercury emissions (mercury ore processing facilities and mercury cell chlor-alkali plants) which have been found to emit mercury in a manner that could cause the ambient concentration to exceed the "safe" level. Section 111 or 112 provides a more appropriate means of controlling the mercury emissions from these two sources, than the Section 108 and 109 comprehensive regulation intended for "numerous or diverse" stationary and mobile sources.

At the time the National Emission Standard for Mercury was promulgated, EPA did not have sufficient data to assess the indirect effects of mercury emissions.[78] The effect of mercury emissions into the atmosphere on the mercury content in water, food, and non-food materials is uncertain. Once the indirect effects of mercury emissions are known, more comprehensive control of mercury emissions into the air, as is found in the National Ambient Air Quality Standards, may be considered by EPA.[79] Whether EPA has the legal authority to issue NAAQS for Section 112 substances like mercury is unclear.

Benzene and Perchlorethylene. The Preamble to the National Emission Standard for Benzene Emissions from Maleic Anhydride Plants reports the rationale for regulating benzene emissions under the authority of Section 112 of the Clean Air Act rather than under Sections 108 and 109.[80] EPA considered regulating benzene only under the ozone NAAQS applicable to photochemical oxidants. According to EPA, State Implementation Plans for reducing volatile organic compounds (VOCs) from maleic anhydride plants could reduce benzene emissions. However, EPA rejected reliance on Sections 108 and 109 for control of benzene emissions for these reasons:

(1) A particular State may not need to control maleic anhydride plants to meet the National Ambient Air Quality Standard, and

(2) A particular State may not need to control benzene emissions to the same extent as may be appropriate for benzene in light of its hazardous nature.[81]

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[78] Preamble to National Emission Standard for Mercury. 38 FR 8825 (April 6, 1973).

[79] Ibid.

[80] 45 FR 26660 (April 18, 1980).

[81] 45 FR 26662 (April 18, 1980).

This reasoning is somewhat misleading because although benzene is a VOC it is not photochemically reactive (See 42 FR 35314, July 8, 1977). However, the same reasoning applies to perchloroethylene which is a reactive VOC and which is to be controlled under a proposed NSPS for both new and existing sources involved in organic solvent cleaning (i.e., degreasing). Perchloroethylene could be regulated under either Section 111 or Section 112, and, because of its effects on the stratospheric ozone layer, even Section 157 could be used as statutory authority. Thus, so long as the applicable statutory criteria are satisfied, EPA may choose among alternative approaches to regulating air pollutants.

Conclusion. Except for the statutory requirements, there are no rigid rules for determining which section of the Clean Air Act would be applied to a particular chemical. EPA has approached the task on a chemical-by-chemical basis. The Agency has examined the characteristics of each chemical considered for regulation to decide which regulatory treatment is most appropriate for the particular chemical. As a result of this chemical-by-chemical approach, there are opportunities for inconsistent applications of the various sections of the Clean Air Act. It appears that EPA, thus far, has sufficiently justified the choice of Clean Air Act sections applied.

CLEAN AIR ACT--REGULATORY REVIEW

The following regulations promulgated or proposed under the authority of the Clean Air Act are reviewed:

- 40 CFR 50--National Primary and Secondary Ambient Air Quality Standards
- 40 CFR 60--Standards of Performance for New Stationary Sources
- 40 CFR 61--National Emission Standards for Hazardous Air Pollutants
- 40 CFR 86--Control of Air Pollution from New Motor Vehicles and New Motor Vehicle Engines
- 40 CFR 87--Control of Air Pollution from Aircraft and Aircraft Engines
- 40 CFR 79--Registration of Fuels and Fuel Additives
- 40 CFR 80--Regulation of Fuels and Fuel Additives.

The regulatory reviews focus on the criteria used by EPA to designate air pollutants and the criteria relied on to establish standards for them.

There are similarities among the regulations concerning the criteria used by EPA such as the use of adverse health effects to justify regulation. However, there also are differences in the manner designated pollutants are treated. For example, EPA is required by the Clean Air Act to establish national ambient air quality standards with "an adequate margin of safety to protect public health". Because neither Congress nor EPA has defined the term "adequate margin of safety" explicitly, the Agency has considerable flexibility in determining what constitutes "an adequate margin of safety".

EPA's flexibility extends to the application of other Clean Air Act provisions to chemicals. In some instances EPA has interpretted the statutory mandate, "to protect public health," to mean the most sensitive population must be safeguarded. In contrast, the Agency has not identified the sensitive population in other rulemaking procedures. Furthermore, EPA has considered synergistic effects of chemicals only when establishing some standards. Similarly, assumptions about the extent of human exposure, e.g., additive exposure, have been made in several, but not all cases. Finally, the types of tests and evidence relied on to conclude that a particular chemical poses a risk to public health vary from one standard setting procedure to another.

The most salient difference among the regulations is the consideration of economic and/or technological feasibility. In some cases EPA is required to consider economic and technological feasibility, e.g. new source performance standards, whereas in other cases standards must be based exclusively on health-related effects, e.g., National Ambient Air Quality Standards. Thus, the role of economic and technical feasibility considerations is examined for each regulatory program reviewed.

NATIONAL AMBIENT AIR QUALITY STANDARDS--
REGULATORY REVIEW

INTRODUCTION

The National Ambient Air Quality Standards (NAAQS), Sections 108, 109, and 110 of the Clean Air Act, provide one means of controlling hazardous air pollutants. This paper summarizes the regulations promulgated under the authority of those sections: 40 CFR 50--National Primary and Secondary Ambient Air Quality Standards. The focus is on the criteria used by EPA to designate chemical substances for which standards are issued; in addition, the factors considered by EPA when establishing ambient air quality standards are examined.

OVERVIEW

To date, EPA has listed seven chemicals under Section 108 of the Clean Air Act. The chemicals and their Code of Federal Regulations citations are:

(1) Sulfur Oxides (40 CFR 50.4, 50.5)
(2) Particulate Matter (40 CFR 50.6, 50.7)
(3) Carbon Monoxide (40 CFR 50.8)
(4) Ozone (40 CFR 50.9)
(5) Hydrocarbons (40 CFR 50.10)
(6) Nitrogen Dioxide (40 CFR 50.11)
(7) Lead (40 CFR 50.12)

Air quality criteria documents for these seven listed chemicals have been issued. The Chemical-By-Chemical Analysis section of this paper summarizes each Air Quality Criteria Document. The emphasis of the summary is on identifying the factors which were instrumental in the establishment of ambient air quality standards. In addition, the promulgated national primary and secondary standards for the seven chemicals are reviewed.

Exhibit 7-5 presents a chronological review of the regulatory and judicial actions related to Sections 108 and 109 of the Clean Air Act. The National Air Pollution Control Administration, Department of Health, Education, and Welfare, was responsible for controlling air pollutants prior to the establishment of EPA. In fact, the original air quality criteria documents for sulfur oxides, particulate matter, carbon monoxide, photochemical oxidants, and hydrocarbons were published by the National Air Pollution Control Administration.

Exhibit 7-6 summarizes the criteria used by EPA to establish primary and secondary ambient air standards. The criteria for listing chemicals under Section 108 are excluded from Exhibit 7-6, because all seven chemicals were listed for the same reasons: (1) they endanger public health and welfare, and (2) they are emitted from numerous or diverse sources.

EXHIBIT 7-5

REGULATORY CHRONOLOGY: NATIONAL AMBIENT AIR QUALITY STANDARDS

Date	Regulatory Action	Federal Register Citation
February 11, 1969	National Air Pollution Control Administration (NAPCA) Issued Air Quality Criteria for Particulate Matter and Sulfur Oxides.	34 FR 1988
March 19, 1970	NAPCA Issued Air Quality Criteria for Carbon Monoxide, Photochemical Oxidants and Hydrocarbons.	35 FR 4768
January 30, 1971	(1) Nitrogen Oxides Listed (2) EPA issued "Air Quality Criteria for Nitrogen Oxides"	36 FR 1515
	(3) EPA proposed Primary and Secondary Standards for Sulfur Oxides, Particulate Matter, Carbon Monoxide, Photochemial Oxidants, Hydrocarbons, and Nitrogen Oxide.	36 FR 1502
April 30, 1971	NAAQS promulgated for Sulfur Oxides, Particulate Matter, Carbon Monoxide, Photochemical Oxidants, Hydrocarbons and Nitrogen Oxides (40 CFR Part 410)	36 FR 8186
November 25, 1971	40 CFR Part 410 regulations republished as 40 CFR Part 50: National Primary and Secondary Ambient Air Quality Standards	36 FR 22384
September 14, 1973	(1) Revocation of Annual Secondary Sulfur Oxide Standard (2) Revision of "Air Quality Criteria for Sulfur Oxides"	38 FR 25678
April 8, 1976	Lead Listed	41 FR 14921
April 20, 1977	EPA reviewing, updating, and revising Air Quality Criteria Documents for Photochemical Oxidants and Hydrocarbons	42 FR 20493

EXHIBIT 7-5
(continued)

REGULATORY CHRONOLOGY: NATIONAL AMBIENT AIR QUALITY STANDARDS

Date	Regulatory Action	Federal Register Citation
December 14, 1977	(1) EPA issued "Air Quality Criteria for Lead" (2) NAAQS proposed for Lead	42 FR 63076
December 16, 1977	External Review Draft of "Air Quality Criteria for Short-Term Exposures to Nitrogen Oxides" available	42 FR 63460
June 22, 1978	(1) Revised "Air Quality Criteria for Ozone and Other Photochemical Oxidants" (2) Changed the Chemical Designation of NAAQS from Photochemical Oxidants to Ozone	43 FR 26962
October 5, 1978	NAAQS promulgated for Lead	43 FR 46246
December 1, 1978	EPA reviewing, updating, and revising "Air Quality Criteria for Carbon Monoxide"	43 FR 56250
December 12, 1978	External Review Draft of Air Quality Criteria Document for Oxides of Nitrogen Available	43 FR 58117
February 8, 1979	NAAQS revised for Photochemical Oxidants	44 FR 8202
July 11, 1979	Second External Review Draft of Air Quality Criteria Document for Oxides of Nitrogen Available	44 FR 40559
October 2, 1979	EPA reviewing, updating, and revising the Criteria Document for Particulate Matter and Sulfur Oxides	44 FR 56730
January 16, 1980	Final Revision of "Air Quality Criteria for Ozone and Other Photochemical Oxidants" issued	45 FR 3107

EXHIBIT 7-5
(continued)

REGULATORY CHRONOLOGY: NATIONAL AMBIENT AIR QUALITY STANDARDS

Date	Regulatory Action	Federal Register Citation
March 10, 1980	External Review Draft of "Facts and Issues Associated with the Need for a Hydrocarbon Criteria Document" Available	45 FR 15262
April 11, 1980	First External Review Draft of "Air Quality Criteria for Particulate Matter and Sulfur Oxides" Available	45 FR 24913
June 18, 1980	EPA Denial of Petition for Reconsideration of Revision of Lead NAAQS	45 FR 41211
June 27, 1980	Lead NAAQS upheld by D.C. Circuit Court of Appeals	
August 18, 1980	(1) Revised NAAQS Proposed for Carbon Monoxide (2) Revised "Air Quality Criteria for Carbon Monoxide" issued	45 FR 55066

EXHIBIT 7-6

National Ambient Air Quality Standards Implementation of Health and Welfare Effects Criteria

A. Primary Standards Health Effects Criteria	Sulfur Oxides	Particulate Matter	Carbon Monoxide	Ozone	Hydrocarbons	Nitrogen Dioxide	Lead
1. Epidemiological Studies of Health Effects	X	X	X	X		X	X
- Synergistic Effects	X	X					
- Long-Term	X	X	X			X	X
- Short Term	X	X	X	X			X
2. Laboratory Observations of Health Effects	X	X	X	X			X
3. Indirect Health Effects					X		
4. Dose-response Relationships			X				X
5. Identified Sensitive Population	X		X	X		X	X
6. Laboratory Animal Studies				X			
7. Non-air Exposures							X
8. Additive Exposure (Cumulative Effects)							X

B. Secondary Standards Adverse Welfare Effects Criteria	Sulfur Oxides	Particulate Matter	Carbon Monoxide	Ozone	Hydrocarbons	Nitrogen Dioxide	Lead
1. Effects on Visibility		X		X			X
2. Effects on Materials		X		X			X
3. Effects on Vegetation	X			X	X	X	X
4. Effects on Public Concern		X					
5. Effects on Climate		X					X

To set primary standards, EPA relied primarily on direct health effects of chemicals. Only in one case, hydrocarbons, were the primary standards based on indirect health effects. Epidemiological (long-term and short-term), laboratory, and laboratory animal studies were the types of data considered by EPA in assessing health effects. The sensitive population was identified in most cases (except for particulate matter and hydrocarbons), and the primary standards were established according to the direct health effects on these particularly sensitive groups. Precise dose-response relationships were available only for carbon monoxide and lead, and served as guides when setting their primary standards. The estimation of allowable air increment of lead was important in deciding that chemical's primary NAAQS, because significant amounts of lead pollutants result from non-air sources. The fact that lead accumulates in the blood stream, resulting in additive exposure, was a key factor in determining the primary standard for lead.

To establish secondary standards, EPA considered only adverse welfare effects. One welfare effect considered was the contribution of air pollutants to visibility impairment. The importance of the effect on visibility is that as visual ranges decrease, operations at airports are increasingly delayed. The effects of air pollutants on materials were instrumental in setting secondary NAQQS. In particular, building material damage, textile damage, and paint damage were the types of effects on materials cited by the Agency when setting secondary standards. Effects on vegetation served as another criteria for the determination of secondary NAAQS. EPA examined visible and subtle effects on vegetation to assess welfare effects. Finally, a few secondary standards were based on the effects of chemicals on climate and public concern.

Exhibit 7-6 clearly illustrates that all secondary NAAQS were not based on the same factors. It is important to note that Exhibit 7-4 does not reflect the welfare effects cited in each air quality criteria document; rather, the Exhibit identifies those welfare effects actually considered by EPA when establishing secondary standards. The Chemical-by-Chemical Analysis section presents more extensive analyses of the standards and the criteria on which they are based.

Exhibit 7-7 summarizes the National Primary and Secondary Ambient Air Quality Standards. The seven pollutants for which standards have been established are listed in the "Pollutant" column. Sulfur dioxide and particulate matter are the only chemicals for which separate primary and secondary standards have been promulgated. It is clear from examining the "Averaging Time" column that short-term and long-term standards have been promulgated for some chemicals, whereas for others only one type has been issued. The frequency parameters are not consistent among chemicals. They vary from an annual geometric mean to an annual maximum not to be exceeded more than once per year. .Exhibit 7-7 also includes the standards expressed in units of micrograms per cubic meter and parts per million (if appropriate).

The most salient characteristic of listing chemical substances under Section 108 and issuing NAAQS under Section 109 of the Clean Air Act is the

EXHIBIT 7-7

Summary: National Primary and Secondary Ambient Air Quality Standards

Pollutant	Type of Standard	Averaging Time	Frequency Parameter	Concentration	
				ug/m^3	ppm
Sulfur Dioxide	Primary	1 year	Annual Arithmetic Mean	80	0.03
		24 hour	Annual Maximum[a]	365	0.14
	Secondary	3 hour	Annual Maximum	1,300	0.5
Particulate Matter	Primary	1 year	Annual Geometric Mean	75	----
		24 hour	Annual Maximum	260	----
	Secondary	1 year	Annual Geometric Mean	60[b]	----
		24 hour	Annual Maximum	150	----
Carbon Monoxide	Primary and Secondary	8 hour	Annual Maximum	10,000	9
		1 hour	Annual Maximum	40,000	35
Ozone	Primary and Secondary	1 hour	Expected days per year	235	0.12
Hydrocarbons	Primary and Secondary	3 hour (6-9 a.m.)	Annual Maximum	160[c]	0.24[c]
Nitrogen Dioxide	Primary and Secondary	1 year	Annual Arithmetic Mean	100	0.05
Lead	Primary and Secondary	90 day	Maximum Arithmetic Mean	1.5	----

[a] Not to be exceeded more than once per year.

[b] As a guide to be used in assessing implementation plans to achieve the 24-hour standard.

[c] As a guide in devising implementation plans to achieve ozone standards.

exclusion of cost and technical feasibility considerations. The listing and the standard must be based solely on scientific/medical criteria. This, in itself, distinguishes the regulation of chemicals under Sections 108 and 109 from other regulatory programs.

For each chemical, all available scientific evidence is compiled in an air criteria document and evaluated by EPA. This procedure allows individual standards to be based on different types and qualities of scientific information.

CHEMICAL-BY-CHEMICAL ANALYSIS

Sulfur Oxides

The "Air Quality Criteria for Sulfur Oxides" paper was published by the National Air Pollution Control Administration in January 1969, and was revised by the Environmental Protection Agency in September 1973. Section 108(c) of the Clean Air Act grants EPA the authority to "review and as appropriate, modify any criteria." In light of new information presented by several studies completed after the initial publication of the Criteria Document in 1969, EPA determined that a revision of the criteria was necessary.

Sulfur oxides, according to the criteria document, include "sulfur oxides, their acids and acid salts." The revised document presents empirical effects of sulfur oxides, primarily sulfur dioxide, based on published scientific studies. The document does not present precise dose-response relationships for various concentrations of sulfur oxides because interactions between sulfur oxides and other pollutants, and sulfur oxides and atmospheric conditions make precise dose-response relationships difficult to measure. Rather, general statements are made about the effects that can be expected when sulfur oxides are present in the atmosphere.

Evaluations of the effects of sulfur oxides on health, visibility, materials, and vegetation are included in the air quality criteria paper. A short discussion of the conclusions from these evaluations follows.

Health Effects. The presence of sulfur oxides in the ambient air is associated with respiratory disease and increased morbidity and mortality rates. This conclusion is "most firm" for short-term air pollution episodes, "probable" for long-term community exposures to air pollution, and "conjectural" for long-term residence in a polluted area. These conclusions were based on analyses of numerous epidemiological studies.[1]

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[1] "Air Quality Criteria for Sulfur Oxides", EPA 1973.

EXHIBIT 7-8

EFFECTS OF SULFUR OXIDES ON HEALTH

Short-Term Effects

(1) AT CONCENTRATIONS OF ABOUT 1500 ug/m^3 (0.52ppm) of sulfur dioxide (24 hour mean), and suspended particulate matter increased mortality may occur.

(2) AT CONCENTRATIONS OF ABOUT 715 ug/m^3 (0.25ppm) of sulfur dioxide and higher (24 hour mean), accompanied by smoke at a concentrtion of 750 ug/m^3 increased daily death rate may occur.

(3) AT CONCENTRATION OF ABOUT 715 ug/m^3 (0.25ppm) of sulfur dioxide (24 hour mean), accompanied by particulate matter, a sharp rise in illness rates for patients over age 54 with severe bronchitis may occur.

(4) AT CONCENTRATIONS OF ABOUT 600 ug/m^3 (about 0.21 ppm) of sulfur dioxide (24 hour mean), with smoke concentrations of about 300 ug/m^3, patients with chronic lung disease may experience accentuation of symptoms.

(5) AT CONCENTRATIONS OF ABOUT 500 ug/m^3 (0.19 ppm) of sulfur dioxide (24 hour mean), with low particulate levels increased mortality rates may occur.

NATIONAL PRIMARY STANDARD = 365 ug/m^3 (0.14 ppm)

(6) AT CONCENTRATIONS RANGING FROM 300 ug/m^3 (0.11 ppm to 0.19 ppm) of sulfur dioxide (24 hour mean), with low particulate levels, increased hospital admissions of older persons for respiratory disease may occur, absenteeism from work, particularly with older persons, may also occur.

Long-Term Effects

(1) AT CONCENTRATIONS OF ABOUT 120 ug/m^3 (0.046 ppm) of sulfur dioxide (annual mean), accompanied by smoke concentrations of about 100 ug/m^3, increased frequency and severity of respiratory diseases in school children may occur.

(2) AT CONCENTRATIONS OF ABOUT 115 ug/m^3 (0.04 ppm) of sulfur dioxide (annual mean), accompanied by smoke concentrations of about 160 ug/m^3 increase in mortality from bronchitis and from lung cancer may occur.

(3) AT CONCENTRATIONS RANGING FROM 105 ug/m^3 to 265 ug/m^3 (0.037 ppm to 0.092 ppm) of sulfur dioxide (annual mean), accompanied by smoke concentration of about 185 ug/m^3, increased frequency of respiratory symptoms and lung disease may occur.

NATIONAL PRIMARY STANDARD = 80 ug/m^3 (0.03ppm).

High particulate levels tend to accompany high sulfur dioxide levels. It is difficult to evaluate precisely the relative contribution of each of these pollutants to health effects.

Exhibit 7-8 lists the health effects of various concentrations of sulfur oxides which served as the basis for the short-term and long-term primary air quality standards. These health effects range from absenteeism from work to increased mortality rates.

Effects on Visibility. According to EPA, it is possible to estimate visibility impairment (for various relative humidities) from sulfur dioxide concentrations although these estimations are not precise. The Agency estimated that at a concentration of 285 micrograms per cubic meter (0.10 ppm) of sulfur dioxide and with a relative humidity of 50 percent, visibility in New York City may be reduced to about 5 miles. The importance of this effect on visibility is that as the visual range decreases below 5 miles, operations at airports are increasingly delayed.

Effects on Materials. Based on laboratory and field studies of steel plate corrosion rates under varying sulfur dioxide concentrations, EPA concluded that considerable corrosion occurs at annual average sulfur dioxide concentrations of 0.03 ppm to 0.12 ppm. Specifically, EPA reported that at a mean sulfur dioxide level of 0.12 ppm, accompanied by high particulate levels,[2] the corrosion rate for steel panels may be increased by 50 percent.

EPA's air quality criteria lists a few other effects of sulfur dioxide on materials. Sulfur oxides pollution:

- contributes to the damage of all types of electrical equipment;
- attacks building materials, e.g., limestone, marble, roofing slate, and mortar;
- discolors and deteriorates statuary and other works of art, certain textile fibers, leather, and paper; and
- adversely effects the durability of oil-based paints.

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[2] High particulate levels tend to accompany high sulfur dioxide levels. It is difficult to evaluate precisely the relative contribution of each of these pollutants to corrosion. However, EPA regards sulfur dioxide as the more important factor in corrosion.

Effects on Vegetation. The vegetational criterion primarily includes scientific studies of vegetational effects resulting from exposure only to sulfur dioxide. Random interactions with other pollutants influence the effects on vegetation, but unfortunately, such information about those effects is limited.[3] In addition, environmental factors such as high humidity, sunlight, soil moisture, and temperature have been implicated in the criteria document as influencing the susceptibility of vegetation injury from sulfur dioxide exposure. However, no scientific studies isolating the relative importance of each environmental factor were cited.

In the criteria document, EPA concludes from available data that growth retardation and yield reduction of vegetation may occur at concentrations greater than 1,300 ug/m^3 (0.5 ppm) over a period of 3 hours.

Revised Criteria Document. EPA submitted a revised draft criteria document for sulfur oxides on April 11, 1980. In the revised document, EPA combined sulfur oxides and particulate matter because these chemicals act together to cause adverse health effects, according to the Agency. The Environmental Defense Fund emphasized the need for more information in the criteria document about:

- what constitutes an adequate safety margin,
- the independent importance of sulfur oxides in health effects,
- the synergism between ozone and sulfur dioxide,
- short-term vs. long-term exposure to sulfur oxides and particulate matter, and
- the non-respiratory adverse health effects, e.g., teratological, reproductive.

EPA plans to complete the revisions to the criteria document by November 1980. At that point, the Agency will determine whether revisions of the sulfur oxides national ambient air quality standards are necessary.

National Ambient Air Quality Standards. The term sulfur oxides is not defined in the regulations; however, sulfur dioxide is specifically designated as the chemical substance to be measured and controlled by the primary and secondary standards. The reason the NAAQS apply only to sulfur dioxide is because sulfur dioxide is:

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[3] Studies of interactions between sulfur dioxide and ozone, and sulfur dioxide and oxides of nitrogen have been cited in the revised criteria document. These studies indicate that mixtures of sulfur dioxide and ozone, as well as sulfur dioxide and nitrogen dioxide produce greater effects on vegetation than sulfur dioxide alone. (38 FR 25680, September 14, 1973.)

- an indicator of the presence of sulfur oxides in polluted air,
- an important index of the effects which have been associated with sulfur oxides, and
- easily measurable.

In 1971, EPA promulgated national primary standards for sulfur oxides. A short-term and a long-term standard were adopted. They are:

(a) 80 micrograms per cubic meter (0.03 ppm) -- annual arithmetic mean.

(b) 365 micrograms per cubic meter (0.14 ppm) -- maximum 24-hour concentration not to be exceeded more than once per year.

Exhibit 7-8 illustrates the relationship between the primary standards and the health effects associated with various concentrations of sulfur dioxide exposure. At the time they were promulgated, EPA claimed these standards provided a "margin of safety adequate to protect the public health" from adverse effects.[4] However, the primary standards were set at a level which would clearly not protect against increased hospital admissions of older persons and absenteeism from work (see (6) from Exhibit 7-8).

The long-term standard, annual mean, is set at a level which should protect against exposures to concentrations of sulfur oxides associated with the long-term health effects mentioned in the 1973 criteria document.

Currently, a major issue is whether the primary standards provide an adequate margin of safety. In addition, interactions between sulfur dioxide and particulates may render the established primary standard insufficiently restrictive to protect public health. As a result, the Agency is considering adopting a short-term, one-to-three hour sulfur dioxide standard based on clinical evidence of adverse "peak" short-term concentrations.[5]

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[4] 36 FR 8186 (April30, 1971).

[5] Environmental Reporter, The Bureau of National Affairs, Inc., August 29, 1980, p. 661.

The secondary standard for sulfur oxides adopted by EPA is 1,300 micrograms per cubic meter (0.5 ppm) maximum 3-hour concentration not to be exceeded more than once per year.

Out of the three possible welfare effects, cited in the criteria document, i.e., effects on visibility, materials, and vegetation, only injury to vegetation was used by EPA to set the secondary standard. The reason is that injury to vegetation is the only welfare effect that can be quantitatively related to ambient concentrations of sulfur oxides. As discussed earlier in the paper, such a precise quantitative relationship is necessary for secondary standards under EPA's interpretation of the statute. Sufficient data are not now available to establish a precise quantitative relationship between specific sulfur dioxide concentrations and corrosion of materials or reduction in visibility.

Particulate Matter

"Air Quality Criteria for Particulate Matter" was first published by the National Air Pollution Control Administration in 1969. The document defined particulate air pollution as "any matter dispersed in the air, whether solid or liquid, in which the individual particles are larger than small molecules but smaller in diameter than 500 u where one u is one millionth of a meter" (u = one micron).[6]

The criteria document identifies and evaluates the effects of particulate matter in the air on health, climate, visibility, materials, vegetation, and public concern.[7] Epidemiological studies cited in the criteria document indicate an association between short-term exposures to certain concentrations of particulate matter and increased mortality and morbidity from damage to the respiratory system. The association between long-term community exposures to particulate matter and respiratory disease incidence is "probable"; furthermore, the association between long-term residence in a polluted area and chronic disease morbidity and mortality is described in the criteria document as "conjectural".[8] Exhibit 7-9 summarizes the National Air

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[6] "Air Quality Criteria for Particulate Matter", NAPCA, January 1969.

[7] As previously explained in the Sulfur Oxides section of this paper, EPA currently is revising the particulate matter criteria document. The first external review draft of "Air Quality Criteria for Particulate Matter and Sulfur Oxides" was made available on April 11, 1980. The revised document combines sulfur oxides and particulates because these substances act together to cause adverse health effects.

[8] This is similar to the evidence of health effects from exposure to sulfur oxides.

EXHIBIT 7-9

EFFECTS OF PARTICULATE MATTER ON HEALTH

Short-Term Effects

(1) AT CONCENTRATIONS OF 750 ug/m³ and higher for particulates on a 24 hour average, accompanied by sulfur dioxide concentrations of 715 ug/m³ and higher, excess deaths and a considerable increase in illness may occur...

(2) IF CONCENTRATIONS ABOVE 300 ug/m³ for particulates persist on a 24 hour average and are accompanied by sulfur dioxide concentrations exceeding 630 ug/m³ over the same average period, chronic bronchitis patients will likely suffer acute worsening of symptoms...

NATIONAL PRIMARY STANDARD = 260 ug/m³

(3) AT CONCENTRATIONS OVER 200 ug/m³ for particulates on a 24 hour average, accompanied by concentrations of sulfur dioxide exceeding 250 ug/m³ over the same average period, increased absence of industrial workers due to illness may occur. . . .

Long-Term Effects

(1) WHERE CONCENTRATIONS RANGE FROM 100 ug/m³ to 130 ug/m³ and above for particulates (annual mean) with sulfur dioxide concentrations (annual mean) greater than 120 ug/m³, children residing in such areas are likely to experience increased incidence of certain respiratory diseases.

(2) AT CONCENTRATIONS ABOVE 100 ug/m³ for particulates (annual geometric mean) with sulfation levels above 30 mg/cm²-mo., increased death rates for persons over 50 years of age are likely...

(3) WHERE CONCENTRATIONS RANGE FROM 80 ug/m³ to 100 ug/m³ for particulates (annual geometric mean) with sulfation levels of about 30 mg/cm²-mo., increased death rates for persons over 50 years of age may occur. . . .

(4) A DECREASE FROM 140 ug/m³ to 60 ug/m³ (annual mean) in particulate concentrations may be accompanied by a decrease in mean sputum volume in industrial workers. . . .

NATIONAL PRIMARY STANDARD = 75 ug/m³

Pollution Control Administration's findings on health effects which were used by EPA to establish the primary standards for particulate matter.

Currently, a major issue concerns the relationship between the size of individual particles and their adverse health effects. Different sizes of particles have different respirable characteristics, and hence, affect the respiratory system differently. It may be advisable to establish national ambient air quality standards which differentiate between sizes of particles on the basis of resulting health effects.

Effects on Climate. Particulate matter absorbs sunlight, produces haze, reduces visibility, and increases rainfall in cities. EPA estimated that concentrations of particulate material from 100-150 micrograms per cubic meter under certain conditions reduce direct sunlight up to one-third in summer and two-thirds in winter.

Effects on Visibility. The primary implications of the reduced visibility caused by particulate matter (and sulfur oxides) are for the safe operation of aircraft. Basically, EPA has determined that particulate concentrations of 150 micrograms per cubic meter, may reduce visibility to as low as 5 miles.

Effects on Materials. Particulate matter corrodes metals, damages electrical equipment, soils and deteriorates buildings and textiles. EPA focused on the corrosion of steel and zinc panels to assess the effects of paticulate matter on materials. Specifically, EPA determined that concentrations of particulate matter ranging from 60 to 180 micrograms per cubic meter accelerate the corrosion of steel and zinc panels.

Effects on Vegetation. EPA examined the effects of individual particulate air pollutants on vegetation rather than the combined effects of the many particulates found in the ambient air. Moreover, this information was not used to establish air quality criteria for particulate matter because the effects on vegetation could not be quantitatively related to particulate levels in the ambient air. EPA presented the information only for the purpose of illustrating possible mechanisms through which particulate matter may affect vegetation.

Effects on Public Concern. The air quality criteria document reviews several studies which indicate a relationship between levels of particulate pollution and levels of public concern over the problem. EPA concluded that concentrations of particulates above 70 ug/m^3 cause public concern for air pollution; this concern increases proportionately with the concentrations of particulate matter.

National Ambient Air Quality Standards. The regulations do not define particulate matter, but the Preamble to the Proposed National Primary and Secondary Standards for Particulate Matter, adopted the definition of particulate matter used in the 1969 criteria document: "any matter dispersed in the air, whether solid or liquid, in which the individual particles are larger than small molecules but smaller than 500 microns."[9]

In 1971, these national primary ambient air quality standards were promulgated for particulate matter:

(a) 75 micrograms per cubic meter--annual geometric mean.

(b) 260 micrograms per cubic meter--maximum 24-hour concentration not to be exceeded more than once per year.

The standards do not differentiate between sizes of particles. In fact, there are no equivalent standards in units of parts per million (ppm) for particulate matter, because the size of particulate matter varies too much to express the standards in terms of ppm.

Exhibit 7-9 illustrates that long-term standard, standard (a), is set at a lower concentration than the concentrations cited in the criteria document as adversely affecting health. For this reason, EPA asserts that the primary standard provides an adequate margin of safety.[10] Standard (b) is set restrictive enough to protect against concentrations shown to cause excess deaths, increased illness, and acute worsening of symptoms for chronic bronchitis patients. However, the short-term standard is not restrictive enough to protect against ambient concentrations which were shown to cause increased absence of industrial workers due to illness.

The national secondary ambient air quality standards for particulate matter are:

(a) 60 micrograms per cubic meter--annual geometric mean.

(b) 150 micrograms per cubic meter--maximum 24-hour concentration not to be exceeded more than once per year.

These secondary standards were selected to protect public welfare against the effects on climate, visibility, materials, and public concern cited in the air quality criteria document.

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[9] 36 FR 1502 (January 30, 1971).

[10] Ibid.

Carbon Monoxide

The first "Air Quality Criteria for Carbon Monoxide" was published in 1970 by the National Air Pollution Control Administration. It includes a toxicological and epidemiological appraisal of atmospheric carbon monoxide (CO).

The toxicological evaluation is based on human exposure studies conducted by Beard and Wertheim.[11] These studies indicate that experimental exposure of non-smokers to 58 mg/m^3 (50 ppm) of carbon monoxide for 90 minutes is associated with high levels of carboxyhemoglobin (COHb) in human blood and impairment in time-interval discrimination.[12] Higher concentrations of carbon monoxide were shown to be associated with significant changes in relative brightness threshold and visual acuity, as well as cardiovascular changes which place an "exceptional burden" on some patients with heart disease.[13]

The epidemiological appraisal identified the segments of the population most susceptible to adverse health effects from atmospheric carbon monoxide. They include the developing fetus and individuals with anemia, cardiovascular disease, abnormal metabolic states such as thyrotoxicosis or fever, and chronic pulmonary disease. In addition, epidemiological evidence was cited which suggests an association between increased fatality rates in hospitalized myocardial infarction patients and exposure to weekly average CO concentrations of the order of 9 to 16 mg/m^3 (8 to 14 ppm).

The 1970 criteria document indicates that associations between ambient levels of carbon monoxide and adverse effects on vegetation, materials, and other aspects of human welfare have not been demonstrated.

Revised Criteria Document. On December 1, 1978 (43 FR 56250), EPA announced that it was in the process of reviewing, updating, and revising the 1970 criteria document for carbon monoxide in accordance with provisions of

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[11] R.R. Beard and G.A. Wertheim. "Behavioral Impairment Associated with Small Doses of Carbon Monoxide," American Journal of Public Health 57:2012-2022, 1967.

[12] High levels of carboxyhemoglobin (COHb) in human blood result in reduced oxygen-carrying capacity of blood since hemoglobin that has combined with CO is not available to transport oxygen. Cardiovascular, central nervous, pulmonary, and other systems are adversely affected by the reduced delivery of oxygen to these systems.

[13] "Air Quality Criteria for Carbon Monoxide", National Air Pollution Control Administration, March 1970.

Section 109(d)(1) of the Clean Air Act. The revised criteria document was published simultaneously with proposed revised standards on August 18, 1980 (45 FR 55066). The significance of the revised criteria document is twofold. First, EPA rejected Beard and Wertheim's toxicological evaluation because attempts to replicate their study had been unsuccessful. Second, a new epidemiological appraisal focused attention on persons with angina and other types of cardiovascular disease, e.g., peripheral vascular disease, as the most sensitive population to low-level, ambient exposures of carbon monoxide.

National Ambient Air Quality Standards. NAAQS for carbon monoxide were promulgated on April 30, 1971. Carbon monoxide is not defined in the regulations.

The primary standards were based on the Beard and Wertheim study cited in the 1970 criteria document. These standards are:

(a) 10 milligrams per cubic meter (9 ppm)--maximum eight-hour concentration not to be exceeded more than once per year.

(b) 40 milligrams per cubic meter (35 ppm)--maximum one-hour concentration not to be exceeded more than once per year.

According to EPA, the national primary standards for carbon monoxide are intended to prevent the occurrence of carboxyhemoglobin levels above 2 percent in human blood. The criteria document points out that COHb levels above 2 percent in human blood affect the central nervous system resulting in impairment in discrimination of time intervals. At the time they were promulgated, EPA believed these standards provided an adequate safety margin for the protection of public health, including the health of persons especially sensitive to the effects of elevated COHb levels.[14]

Adverse welfare effects have not been observed to occur at concentration levels below the levels established for the primary standards. Hence, the secondary standards were specified at the same levels as the primary standards.

Revised Standards. After developing the revised criteria document, EPA proposed revised NAAQS for CO on August 18, 1980 (45 FR 55066). The Agency proposed to retain the existing primary 8-hour standard at 9ppm and to lower the primary 1-hour standard from 35 ppm to 25 ppm. A more restrictive 1-hour standard is necessary, according to EPA, because of the more rapid accumulation of blood carboxyhemoglobin in moderately exercising sensitive persons compared to resting individuals. The impact of exercise was not considered when the original standard was established in 1971.

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[14] 36 FR 8186 (April30, 1971). Preamble to Carbon Monoxide NAAQS.

Based on medical evidence presented in the criteria document, no clear threshold of adverse health effects can be identified with certainty for COHb levels; rather, a continuum exists consisting of COHb levels shown to be associated with adverse health effects, and levels where health effects are less certain and more difficult to identify. Thus, selecting a standard that takes into account the known continuum of effects "is a judgment of prudent public health practice, and does not imply some discrete or exact margin of safety appended to a known threshold."[15]

EPA rejected the option of setting a zero-level standard as an expedient means of protecting public health without having to decide among uncertainties. It is the Agency's belief that Congress did not intend EPA to "take the easy way out" simply because the health evidence supporting a standard above zero is beset with uncertainties. Thus, the Agency based the decision as to what standard protects public health with an adequate margin of safety on a consideration of the uncertainty that any given level is low enough to protect adverse health effects and on the relative acceptability of various degrees of uncertainty, given the seriousness of the effects (45 FR 55072).

To determine how much the 1-hour standard should be reduced, EPA employed the Coburn equation[16] which permits the estimation of COHb levels that will result from short-term (one- to eight-hour) exposures to ambient CO concentrations.

EPA focused on the most sensitive population, i.e., individuals with cardiovascular heart or peripheral vascular disease, when applying the Coburn equation. The results of this analysis indicate that more than 99 percent of the sensitive group would not be expected to reach, or exceed, 2.1 percent COHb upon exposure to an air quality associated with the proposed standards of 9 ppm averaged over eight hours or 25 ppm averaged over 1 hour. Since the lowest group mean COHb level convincingly linked to adverse health effects is in the range of 2.7 to 2.9 percent and the proposed standards protect against exceeding 2.1 percent COHb, then, the proposed standards should protect against demonstrated adverse health effects. The proposed standards do not afford a large degree of protection for the sensitive population, so EPA currently is soliciting comments from the public about whether the one-hour and eight-hour standards provide an adequate margin of safety.

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[15] Preamble to Proposed Revision of CO NAAQS, 45 FR 55072, (Augut 18, 1980).

[16] R.F. Coburn, R.E. Foster, and P.B. Kane, "Considerations of the Physiology and Variables that Determine the Blood Carboxyhemoglobin Concentrations in Man," Journal of Clinical Investigation, 44:1899-1910, 1965.

To determine the margin of safety, EPA considered that uncertainties exist regarding:

- the lowest adverse health effect levels from CO, as a result of variations in individual susceptibilities and the absence of negative clinical studies in the range of lower CO levels;
- additional potentially sensitive groups including fetuses, pregnant women, anemics, visitors to high altitude locations, and persons on certain medications;
- the accuracy of the Coburn equation and EPA estimates;
- adverse health effects that may result from very short duration high-level CO exposures (the bolus effect); and
- possible interactions between CO and other pollutants.

The proposed standard specifies a statistical standard rather than the current deterministic (once-per-year) standard. EPA believes that expressing the standard in terms of the expected number of exceedances per calendar year is more practical and logical than the deterministic approach. The revised ozone standard (43 FR 26967) also uses the expected exceedances format.

Another change proposed in the revised standards, is to use a daily interpretation for exceedance of the CO standard, so the exceedances will be determined on the basis of the number of days on which one- or eight-hour concentrations are above the standard levels.[17] This approach also is consistent with the revised ozone standard.

The eight-hour averaging time was selected for the standard because most individuals achieve equilibrium levels of COHb after 8 hours of exposure. In addition, most people are exposed to CO in 8-hour blocks of time (e.g., work, sleep). The one-hour averaging time was selected primarily because several scientific studies have demonstrated adverse health effects for sensitive persons after one- to two-hour exposures to carbon monoxide.

Finally, EPA proposes to rescind the existing secondary standard because CO concentrations of the magnitude necessary to produce detrimental effects to vegetation are rarely if ever observed in the ambient air. The Agency believes no secondary standard is necessary to protect public welfare from ambient CO exposures (45 CFR 55076).

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[17] EPA prefers the daily interpretation because it simplifies daily reporting by eliminating a data step.

Ozone (Photochemical Oxidants)

The first air quality criteria document for photochemical oxidants was published by the National Air Pollution Control Administration in 1970. EPA promulgated National Ambient Air Quality Standards for photochemical oxidants in April 1971. In accordance with the provisions of Section 109(d)(1) of the Clean Air Act, EPA in 1977 began reviewing and updating the 1970 criteria document. This led to a revised version of the air criteria document published by EPA in April 1978 and entitled "Criteria for Ozone and Other Photochemical Oxidants". Summaries of the key issues addressed by the revised air criteria document follow.

Photochemical Oxidant Precursors. Photochemical oxidants result from sunlight acting on volatile organic compounds (VOC) and oxides of nitrogen. EPA issued a recommended policy for States to follow on the control of volatile organic compounds as constituents in the formation of photochemical oxidants (42 FR 35314, July 8, 1977). This policy recommends the reduction of VOC in surface coatings, process changes, and the use of control equipment in order for States to meet oxidant NAAQS. Four compounds were recommended for exclusion from control because of their negligible photochemical reactivity. They are:

- Methane
- Ethane
- 1,1,1-Trichloroethane (Methyl Chloroform)
- Trichlorotrifluoroethane (Freon 113)

The twelve compounds listed below are VOC of low photochemical reactivity. These VOC should be controlled under EPA policy, but priority should be given to controlling more reactive VOC first.

- Propane
- Acetone
- Methyl Ethyl Ketone
- Methanol
- Isopropanol
- Methyl Benzoate
- Tertiary Alkyl Alcohols
- Methyl Acetate
- Phenyl Acetate
- Ethyl Amines
- Acetylene
- N,N-dimethyl formamide

Health Effects. "Criteria for Ozone and Other Photochemical Oxidants" assesses the human health effects from atmospheric ozone in terms of the mechanical function of the lung, oxidant effects on asthmatics, respiratory symptoms and headaches, eye irritation, mortality, susceptibility to bacterial infection, acceleration of the aging process, and biochemical effects. In brief, experimental and epidemiological studies are cited in the air criteria document to support EPA's conclusions that:

(1) Experimental ozone exposures at concentrations of 0.30 ppm are associated with changes in lung function that result in physical discomfort which, even among healthy people (and especially in people with respiratory illness), may restrict normal activity or impair the performance of tasks.

(2) Asthmatics represent the principal sensitive group of concern in setting the primary standard, since available evidence suggests that an elevated proportion of asthmatics experience attacks on days when the peak hourly oxidant concentrations exceed 490 ug/m^3 (0.25 ppm).

(3) Short-term ozone exposures between 0.15 and 0.25 ppm result in respiratory symptoms including throat tickle, chest tightness, coughing, wheezing and headache; respiratory symptom severity increases with ozone concentration and exercise.

(4) Ozone alone at ambient concentrations is not an eye irritant, but the total photochemical oxidant mix is associated with eye irritation; an ozone standard will reduce eye irritation because control measures to reduce ozone will also reduce the eye irritation components of photochemical oxidants.

(5) No studies have conclusively linked exposure to ozone or photochemical oxidants with an increase in human mortality.

(6) Decreased resistance to bacterial infection probably occurs in humans as a result of ozone exposure; this health effect has been demonstrated by an increased rate of mortality in laboratory animals subjected to both a bacterial challenge and exposures to ozone, so the exact concentrations which are associated with increased susceptibility to bacterial infection in humans are not known.

(7) Ozone may accelerate the aging process in living organisms by inducing premature aging symptoms such as premature cartilage calcification, and severe depletion of body fat.

(8) Exposures of human subjects to ozone produces changes in blood biochemistry, including increased fragility of red blood cells, and altered enzyme activities in the serum but these changes have not been linked to any clinical diseases.

Effects on Vegetation. According to the air quality criteria document the effects of ozone on plants include visible foliar injury, increased leaf drops, reduced plant vigor, reduced plant growth, and death. The responses of plants to ozone exposures are not linearly dependent on the dose; short-term exposures at a given dose are more damaging than long-term exposures.

Effects on Visibility. There is limited data suggesting an association between ambient ozone and visibility degradation.

Effects on Materials. Ozone accelerates the deterioration of rubber, textile dyes and fibers, and certain paints. The effects of ozone on materials are linearly dependent on the total dose sustained by the material.

National Ambient Air Quality Standard. EPA's objective in setting primary NAAQS is to select an ozone concentration that accurately considers the existing medical evidence and the uncertainties in this evidence, and thus, will protect all population groups with an adequate margin of safety.[18] EPA, after considering all the scientific evidence presented in the air quality criteria document, is forced to make judgments about the level below the probable adverse health effect level that provides an adequate margin of safety for sensitive persons.[19] The Agency considered the "seriousness of the effects" when deciding what standard protects public health with an adequate margin of safety. On April 30, 1971, EPA promulgated primary NAAQS for photochemical oxidants which were:

> based on evidence of increased frequency of asthma attacks in some asthmatic subjects on days when estimated hourly average concentrations of photochemical oxidant reached 0.10 ppm.[20]

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[18] 44 FR 8213, (February 8, 1979).

[19] Preamble to Photochemical Oxidants NAAQS, 44 FR 8213, (February 8, 1979).

[20] Preamble to NAAQS for Photochemical Oxidants, 36 FR 8186, April 30, 1971.

The standards were not directed at the other sensitive group, persons engaging in exercise, because the validity of the data suggesting impairment of athletic performance at various oxidant concentrations was questioned by EPA. The 1971 primary standard was set at 0.08 ppm as a one-hour average, because EPA believed this level allowed "a margin of safety which is substantially below the most likely threshold level suggested by the data."

The 1978 revised air criteria document led EPA to conclude that the most probable level for adverse health effects in sensitive persons, as well as in healthier persons who are exercising vigorously, falls in the range of 0.15 to 0.25 ppm. Based on these findings, EPA proposed to raise the primary standard from 0.08 ppm to 0.10 ppm in June 1978. After receiving "informed scientific opinion", the Agency concluded that 0.10 ppm provided a wider margin of safety than was necessary to protect public health.[21] Thus, EPA promulgated a revised primary standard of 0.12 ppm on February 8, 1979. According to EPA, the 0.12 ppm standard is "necessary and sufficiently prudent" to protect public health.[22] The standard is attained when the expected number of days per calendar year with maximum hourly average concentrations above 0.12 ppm is equal to or less than 1.

The April 1971 standard was established for the entire class of photochemical oxidants, but there were not satisfactory methods for accurately and reliably measuring this collective class of pollutants. The reference method cited in the regulations to estimate ambient oxidant levels and determine compliance with the standard measured only ozone (not the total oxidant mix). As a result, in the revised NAAQS promulgated on February 8, 1979, EPA redesignated the standard from photochemical oxidants to ozone. Thus, the revised standards are entitled, "National Primary and Secondary Ambient Air Quality Standards for Ozone."

EPA based the secondary ozone air quality standard on information available concerning growth and yield reduction in commercially important crops and indigenous vegetation exposed to ozone under field conditions.[23] From the available data, EPA concluded that there is no evidence of a significant decrease in growth or yield of commercially important crops or indigenous flora at the primary standard concentration level (0.12 ppm). EPA decided that a secondary standard more stringent than the primary standard is not necessary to prevent ozone-related yield reduction effects in vegetation. Furthermore, EPA determined that there would be no measurable reduction in materials damage if a more stringent secondary standard level were selected;

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[21] 44 FR 8217 (February 8, 1979).

[22] Ibid.

[23] 44 FR 8217 (February 8, 1979).

EPA also determined that a secondary ozone standard more stringent than the primary standard is not necessary to prevent visibility degradation. In conclusion, the secondary ambient air quality standard for ozone is the same as the primary standard--12 ppm.

Hydrocarbons

"Air Quality Criteria for Hydrocarbons" was published by the National Air Pollution Control Administration in March 1970. The criteria for hydrocarbons[24] result primarily from their role as precursors of other compounds formed in the atmospheric photochemical system and not from the direct effects of hydrocarbons themselves. This is allowed under the Clean Air Act where the key factor is for a chemical to "contribute to air pollution which may reasonably be anticipated to endanger public health or welfare."

EPA, currently, is reviewing a draft criteria document for hydrocarbons (45 FR 15262, March 10, 1980). This draft argues against revising the 1970 criteria document, because EPA believes that hydrocarbons at current ambient levels do not pose significant health or welfare risks. The Agency maintains that the 1971 standards adopted for hydrocarbons have successfully assisted states in determining the level of hydrocarbon emission reductions necessary to meet the ozone NAAQS.

Health Effects. No direct health effects from hydrocarbons in the ambient air on populations have been documented. However, ambient levels of hydrocarbons are indirectly related to health effects attributed to photochemical smog, e.g., eye irritation, respiratory symptoms.

The criteria document shows that nonmethane hydrocarbon concentrations of 200 ug/m^3 for the three hour period from 6:00 to 9:00 a.m. can be expected to produce a maximum hourly average concentration of ozone up to 200 ug/m^3 (0.1 ppm). This level of ozone, 0.1 ppm, is below the 0.15 ppm concentration viewed as the most probable level for adverse health effects in sensitive persons (see previous section on Ozone). However, given the effects on ozone from other actors in the atmospheric photochemical system, the criteria document concludes that hydrocarbon contribution of up to 0.1 ppm of ozone must be controlled in order to protect public health from the adverse effects of ozone.

Effects on Vegetation. Studies cited in the criteria document report that injury to sensitive plants is associated directly with ethylene (a hydrocarbon) concentrations of from 1.15 to 575 ug/m^3 (0.001 to 0.5 ppm) over a time period of 8 to 24 hours.

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[24] The air quality criteria document defines this group of air pollutants as "gas-phase hydrocarbons and certain of their oxidation products, particularly aldehydes."

National Ambient Air Quality Standards. The sole purpose of prescribing hydrocarbon standards[25] is to control photochemical oxidants.[26] When promulgating primary air quality standards for hydrocarbons, EPA examined their contribution to the formation of photochemical oxidants. In this way, the health effects indirectly resulting from hydrocarbons served as the basis for establishing the primary standards.

EPA established the national primary standard for hydrocarbons at 160 micrograms per cubic meter (0.24 ppm)--maximum three-hour concentration (6 to 9 am) not to be exceeded more than once per year. EPA determined that this ambient air concentration of hydrocarbons would permit states to meet the ozone NAAQS.

The secondary standards for hydrocarbons were established at the same concentration level as the primary standards--160 ug/m^3. It is EPA's belief that a more stringent standard is unnecessary because adverse welfare effects have not been observed to occur at levels below the levels of the primary standards.

Nitrogen Oxides

"Air Quality Criteria for Nitrogen Oxides" was published by the Environmental Protection Agency in January 1971. The document discusses only the direct effects of nitrogen oxides and not the indirect effects through the photochemical reaction mechanism. Effects of both nitric oxide and nitrogen dioxide, are included in the criteria document, but the promulgated standard applies only to nitrogen dioxide. Consequently, this paper will summarize only that portion of the air criteria document dealing with nitrogen dioxide (NO_2).

Under the Clean Air Act Amendments of 1977 Section 108(c) , EPA was required to review the need for a short-term, at most three-hour, ambient nitrogen dioxide standard. In addition, Section 109(c) directs EPA to adopt a short-term primary standard for NO_2 if the scientific evidence indicates such a standard is necessary. In accordance with the 1977 Amendments, EPA issued a document entitled, "Health Effects of Short-Term Exposure to Nitrogen Dioxide" on December 19, 1977 (42 FR 63460). Thus far, a short-term standard for NO_2 has not been promulgated.

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[25] The promulgated standard applies to all hydrocarbons, but the term "hydrocarbons" is not defined in the regulations.

[26] 36 FR 8186 (April 30, 1971).

On December 12, 1978, EPA announced the availability of the first external review draft of the revised criteria document for oxides of nitrogen. The second external review draft was made available on July 11, 1979. No final revision of the criteria document has been issued.

Exhibit 7-10 outlines the health effects of nitrogen dioxide which served as the basis for the long-term primary air quality standard. The intensity of the response to nitrogen dioxide was given little consideration in assessing potential health risks to various concentrations of NO_2.

Effects on Vegetation. The air criteria document discussed three effects on vegetation. They were:

(1) Exposure to 470 ug/m^3 (0.25 ppm) of nitrogen dioxide for eight months caused leaf abscission and decreased yield among navel oranges.

(2) Exposure to nitrogen dioxide concentrations of 940 ug/m^3 (0.5 ppm) for 35 days resulted in leaf abscission and chlorosis on citrus fruit trees.

(3) Exposure to nitrogen dioxide concentrations of 1.9 mg/m^3 (1 ppm) for one day can cause overt leaf injury to sensitive plants.

Effects on Materials. Damage to materials, particularly the corrosion of electrical components, has been attributed to nitrogen dioxide in ambient atmospheres, but the precise concentrations producing these effects has not been determined.

National Ambient Air Quality Standards. The primary standard for nitrogen dioxide is 100 micrograms per cubic meter (0.05 ppm) annual arithmetic mean. The level of this standard is more restrictive than the health-effect-related value of 113 ug/m^3 (0.06 ppm) yearly average, cited above. No short-term standard for NO_2 has been promulgated yet to protect human health from the short-term exposure effects listed in Exhibit 7-8.

EPA set the secondary standards at the same level as the primary standard--100 ug/m^3. This level, according to EPA, will prevent the effects on vegetation listed above.

Lead

"Air Quality Criteria for Lead" was published by the Environmental Protection Agency in December 1977 as a result of a law suit brought against EPA by the Natural Resources Defense Council (NRDC) in 1975. The Court ruled in favor of NRDC, and ordered EPA to list lead as a pollutant under Section 108 of the Clean Air Act. EPA listed lead on March 31, 1976, and then developed the air quality criteria. Prior to the lawsuit, EPA intended to

EXHIBIT 7-10

HUMAN HEALTH EFFECTS OF NITROGEN DIOXIDE

(1) Short-Term Exposure. Limited studies show that exposure to NO_2 for less than 24 hours continuously can have several concentration-dependent effects.

1. The olfactory threshold value of NO_2 is about 225 ug/m^3 (0.12 ppm).

2. Exposure to 9.4 mg/m^3 (5 ppm) for 10 minutes has produced transient increase in airway resistance.

3. Occupational exposure to 162.2 mg/m^3 (90 ppm) for 30 minutes has produced pulmonary edema 18 hours later, accompanied by an observed vital capacity that was 50 percent of the value predicted for normal function.

(2) Long-Term Exposure. An increased incidence of acute respiratory disease was observed in family groups when the mean range of 24-hour NO_2 concentrations, measured over a 6-month period, was between 117 and 205 ug/m^3 (0.062 and 0.109 ppm) and the mean suspended nitrate level[a] during the same period was 3.8 ug/m^3 or greater.

The frequency of acute bronchitis increased among infants and school children when the range of mean 24-hour NO_2 concentrations, measured over a 6-month period, was between 118 and 156 ug/m^3 (0.063 and 0.083 ppm) and the mean suspended nitrate level during the same period was 2.6 ug/m^3 or greater.

Yearly average NO_2 concentrations exceed the Chattanooga healtheffect-related value of 113 ug/m^3 (0.06 ppm) in 10 percent of cities in the United States with populations of less than 50,000, 54 percent of cities with populations between 50,000 and 500,000, and 85 percent of cities with populations over 500,000.

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[a] Suspended nitrates are particulate matter.

control lead in the air by limiting emissions from automobiles and by controlling emissions from certain categories of industrial point sources under Section 111.

Health Effects. The air criteria document reviewed the toxic effects of lead resulting from high levels of exposure. These include colic, palsy, and encephalopathy. In addition, the longer-term, low level exposure effects were examined. These low-exposure-level effects are listed in Exhibit 7-11. According to the criteria document, lead accumulates in the human body throughout life. Blood lead concentrations respond to changes in the level of environmental exposure; the threshold for a particular health effect is defined as the blood lead level at which the effect is first detected.

The criteria document identifies several groups for which lead exposure poses a greater risk than for the general population. These include young children, pregnant women and the fetus, the occupationally exposed, and individuals suffering from dietary deficiencies or exhibiting the genetic inability to produce certain blood enzymes.

Welfare Effects. The criteria document cites scientific evidence which demonstrates that animals are not more susceptible to adverse effects from lead than humans and that adverse effects in animals do not occur at lower levels of exposure than comparable effects in humans. (Grazing animals may be exposed to lead deposited on the leaves of plants.) The document presents data indicating that atmospheric sources of lead may be injurious to plants, since the chemical is absorbed by plants from soil. It is pointed out, however, that lead is generally in a form that is not available to plants. There is no evidence presented in the paper to indicate that ambient levels of lead result in significant damage to materials. Finally, the document describes the effects of lead on visibility and climate as "minimal".

National Ambient Air Quality Standards. In developing the primary standard, EPA made several policy determinations which are summarized in Exhibit 7-12. EPA determined that young children (aged one to five years) are the group within the general population that is particularly sensitive to lead exposure.

To determine the pivotal adverse health effect, EPA examined the criteria document. The document indicates that the lowest blood level of lead for functional impairment is 15 to 20 ug Pb/dl. EPA also determined that the mean population blood lead level for children should not exceed 15 ug Pb/dl. This is the lowest value presented in the criteria document as a threshold below which the sensitive population as a group (children) has not shown a functional impairment due to lead and above which there are increasing implications for health.

To estimate the relationship between air lead exposure and resulting blood lead levels, the criteria document concludes:

EXHIBIT 7-11

LOW-EXPOSURE HEALTH EFFECTS OF LEAD

Lowest Level For Observed Effects (ug Pb/dl Whole Blood) a/	Observed Effect	Population Group
10	ALAD inhibition b/	Children and adults
15 to 20	Free erythrocyte porphyrin elevation	Women and children
20 to 25	Free erythrocyte porphyrin elevation	Adult Males
40	Increased urinary ALA excretion	Children and adults
40	Anemia	Children
40	Coproporphyrin elevation	Adults and children
50	Anemia	Adults
50 to 60	Cognitive (CNS) deficits	Children
50 to 60	Peripheral neuropathies	Adults and children
80 to 100	Encephalopathy symptoms	Children
100 to 120	Encephalopathy symptoms	Adults

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a/ ug Pb/dl is micrograms of lead per deciliter of blood.

b/ Inhibition of the enzyme aminolevulinic acid dehydratase (ALAD) represents the lowest level effect of lead that has been detected (10 ug Pb/dl). ALAD inhibition at this level is not regarded as a physiological impairment of the system. Thus, 15 to 20 ug Pb/dl is regarded as the lowest level effect of lead that is associated with functional impairment.

EXHIBIT 7-12

EPA CONSIDERATIONS IN DEVELOPING THE LEAD PRIMARY STANDARD

Judgments	Final Decisions
Determining the critically sensitive population	Young Children (ages 1-5 years)
Determining the pivotal adverse health effect	Functional Impairment (15 to 20 ug Pb/dl)
Determining the mean population blood lead level which would be consistent with protection of the sensitive population	Threshold for Functional Impairment (15 ug Pg/dl)
Determining the relationship between air lead exposure and resulting blood lead level	1 ug Pb/m^3 air : 2 ug Pb/dl blood
Determining the allowable blood lead increment from air	3 ug Pb/dl

> "Evidence [from clinical and epidemiological studies] indicates that a positive relationship exists between blood and air lead levels, although the exact functional relationship has not yet been clarified. Available data indicate that in the range of air lead exposures generally encountered by the population, the ratio of the increase in blood lead per unit of air lead is from 1 to 2. The range of ratios for children's blood lead response to a one ug increase in air lead is from 1.2 to 2.3."

To clarify this statement, the ratios between air lead exposures and blood levels range from 1:1 to 1:2. For chidren, this ratio ranges from 1:1.2 to 1:2.3. EPA selected a ratio of 1:2 to calculate the impact of air lead levels on blood lead levels in children.

Finally, EPA had to determine the allowable blood lead increment from air, since significant amounts of the lead pollutant result from non-air sources. This aspect of developing the ambient standard for lead distinguishes it from all other pollutants previously addressed by EPA under Section 109 of the Clean Air Act. The level selected as the basis for determining the allowable contribution from air is a policy choice rather than an exact calculation. The reason for this is that the non-air contribution to blood lead varies from time to time and place to place. Thus, EPA must make a policy choice which reflects how much of the lead pollution problem should be controlled through air pollution control programs.

From evaluating the epidemiological and isotopic tracing studies presented in "Air Quality Criteria for Lead", EPA concluded that approximately two-thirds of blood lead is typically derived from non-air sources. Since the average blood lead level in areas where air lead exposure is low is 12.7 ug Pb/dl, EPA assumed that 12 ug Pb/dl of the blood lead level in children results from non-air lead sources.

To calculate the air standard EPA estimated the allowable contribution to blood lead from air sources to be:

Allowable Total Lead Exposure	-	Contribution from Non-Air Sources	=	Allowable Contribution from Air Sources
(15 ug Pb/dl)	-	(12 ug Pb/dl)	=	3 ug Pb/dl

The air lead concentration consistent with the blood lead contribution from air sources was estimated to be:

$$\text{Allowable Contribution from Air Sources} \times \text{Ratio of Air Lead Levels to Blood Lead Levels} = \text{Primary Standard}$$

$$3\ \text{ug Pb/dl} \times \frac{1\ \text{ug Pb/m}^3\ \text{air}}{2\ \text{ug Pb/dl blood}} = \underline{1.5\ \text{ug Pb/m}^3}$$

Hence, the primary ambient air quality standard for lead is 1.5 ug Pb/m^3, maximum arithmetic mean averaged over a calendar quarter.

EPA selected a calendar quarter as the averaging period for the standard to protect against variations in exposure which could result in adverse effects. EPA originally proposed an averaging period of a calendar month, but extended the time period to a calendar quarter to improve the validity of lead air quality data gathered to monitor progress toward attainment of the standard. The Agency believes extending the averaging period to a calendar quarter will not significantly reduce the protectiveness of the standard. This conclusion is based on the following factors:[27]

(1) From actual ambient measurements, there is evidence that the distribution of air lead levels is such that if the quarterly average was achieved there is little possibility that there could be sustained periods greatly above the average value.

(2) It seems likely that where elevated air lead levels do occur, they will be close to point or mobile sources. Typically, young children will not encounter such levels.

(3) There is medical evidence indicating that blood lead levels equilibrate slowly to changes in air exposure. This serves to dampen the impact of a short-term period of exposure to elevated air lead.

(4) Direct exposure to air is only one of several routes of total exposure. This lessens the impact of a change in air lead on blood lead levels.

EPA based the secondary standard on the welfare effects described in the criteria document. The Agency concluded that the primary ambient air standard would protect the public welfare adequately and EPA promulgated the secondary standard at 1.5 ug Pb/m^3.

Legal Challenges. The Lead Industries Association legally challenged the national ambient air quality standard for lead. The federal appeals court ruled in favor of EPA on June 27, 1980. The court ruled that EPA is not required to consider economic and technological feasibility in adopting the ambient standards. The court decided that EPA's determinations of adverse health effects from lead concentration levels were "not arbitrary or capricious and were supported by the evidence".[28] This court decision affirms EPA's current procedure for establishing national ambient air quality standards.

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[27] Preamble to the NAAQS for Lead, 43 FR 46255 (October 5, 1978).

[28] Lead Industries Association v. EPA, 14 ERC 1906 (D.C. Cir. 1980), cert. den. ____ U.S. _____ (1980).

NEW SOURCE PERFORMANCE STANDARDS--REGULATORY REVIEW

INTRODUCTION

This section reviews the New Source Performance Standards (NSPS) promulgated under the authority of Section 111 of the Clean Air Act in order to:

- identify the chemical substances which have been designated for regulation under Section 111, and
- examine the designation criteria used by EPA.

First, the requirements for establishing new source performance standards are reviewed. Then, the specific pollutants addressed by these standards are identified and the designation criteria specified.

OVERVIEW

The Standards of Performance for New Stationary Sources promulgated under the authority of Section 111 are located in 40 CFR 60. Thus far, twenty-nine source categories have been regulated. NSPS currently adopted include these three types:

(1) emission limitations for a given source category,

(2) specified percentage reductions in emissions, and

(3) equipment, work practice, etc. standards.

The third type of standard applies in cases where it is not feasible to prescribe or enforce a standard of performance. In such cases, EPA is authorized under Section 111(h)(1) to promulgate "a design, equipment, work practice, or operational standard, or combination thereof which reflects the best technological system of continuous emission reduction."

In accordance with the legislative purpose and statutory requirements, new source performance regulations are organized according to sources rather than according to pollutants. All emissions of all pollutants from a stationary source and their effects on public health and welfare may be considered by EPA when determining whether to regulate the source category. If EPA determines that the emissions from a source category have the potential to endanger public health or welfare, then the category is regulated under Section 111. This determination may be made before or after the Agency has identified which specific pollutants in the total emission pool are responsible for the "potential to endanger public health or welfare." However, in general, sources are designated for regulation because specific chemicals believed to pose health and welfare risks are identified in their emissions.

DESIGNATED POLLUTANTS

Each new source performance standard issued through January 1, 1981, includes emission limits for one or more of the following pollutants:

- Particulate Matter
- Sulfur Dioxide
- Nitrogen Oxides
- Carbon Monoxide
- Volatile Organic Compounds (VOC)
- Sulfuric Acid Mist
- Fluorides
- Total Reduced Sulfur (TRS)
- trichlorethylene
- perchloroethylene
- 1,1,1 trichloroethane
- methylene chloride
- trichlorotrifluroethane

These chemicals or classes are referred to as "designated pollutants". This is to distinguish them from the "criteria pollutants" regulated under Section 109 and "hazardous air pollutants" which are regulated under Section 112.

The designated pollutants are defined as:

(1) Particulate Matter which means any finely divided solid or liquid material, other than uncombined water (as measured by specified reference methods, or an equivalent or alternative method) (40 CFR 60.2).

(2) Sulfur Dioxide which is not defined in the regulations.

(3) Nitrogen Oxides which means all oxides of nitrogen except nitrous oxide, as measured by specified test methods (40 CFR 60.2).

(4) Carbon Monoxide which is not defined in the regulations.

(5) Volatile Organic Compounds which means any organic compound that when released to the atmosphere can remain long enough to participate in photochemical reactions (44 FR 49223, August 21, 1979).

Volatile Organic Compounds of negligible photochemical reactivity include:[1]

- Methane
- Ethane
- 1,1,1- Trichloroethane (Methyl Chloroform)
- Trichlorotrifluoroethane (Freon 113).

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[1] 42 FR 35314 (July 8, 1977).

Volatile Organic Compounds of low photochemical reactivity which only participate in photochemical reactions during multiday stagnations include:[2]

- Propane
- Acetone
- Methyl Ethyl Ketone
- Methanol
- Isopropanol
- Methyl Benzoate
- Tertiary Alkyl Alcohols
- Methyl Acetate
- Phenyl Acetate
- Ethyl Amines
- Acetylene
- N,N-dimethyl formamide

(6) Sulfuric Acid Mist expressed as H_2SO_4, which means acid mist (as measured by Method 8 of Appendix A to the regulations, or an equivalent or alternative method) (40 CFR 60.81).

(7) Fluorides which means total fluorides which are elemental fluorine and all fluoride compounds (as measured by reference methods specified in 40 CFR 60.195 or by equivalent or alternative methods) (40 CFR 60.191).

(8) Total Reduced Sulfur which means the sum of the sulfur compounds hydrogen sulfide, methyl mercaptan, dimethyl sulfide, and dimethyl disulfide, that are released during the kraft pulping operation and measured by Reference Method 16 (40 CFR 60.281).

(9) Trichloroethylene, Perchloroethylene, 1,1,1 Trichloroethane, Methylene Chloride, and Trichlorotrifluroethane are halogenated solvents designated under the proposed NSPS for organic solvent cleaners and were not further defined through CAS numbers or synonyms.[3]

It should be noted that new source performance standards have been promulgated to control visible emissions in addition to the eight designated pollutants. Visible emissions in air constitute a physical safety hazard (e.g., like noise) but are not hazardous due to their chemical composition. Consequently, these standards are not reviewed here.

Since one purpose of new source performance standards is to assure that new sources do not prevent the attainment or maintenance of National Ambient

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[2] *Ibid*.

[3] See 45 FR 39766 (June 11, 1980).

Air Quality Standards, EPA established NSPS for five of the seven criteria pollutants. These five are particulate matter, sulfur dioxide, nitrogen oxides, carbon monoxide, and volatile organic compounds. Volatile organic compounds are considered a criteria pollutant because they include hydrocarbons and because they contribute to ambient levels of photochemical oxidants. Hence, the designation of these five chemicals for regulation under Section 111 was based on their designation as criteria pollutants, and thus, on the evidence of health and/or welfare effects cited in the Air Quality Criteria Documents prepared under Section 109. A thorough discussion of these health and welfare effects can be found in the National Ambient Air Quality Standards Regulatory Review.

EPA cited health-related effects as the rationale for including sulfuric acid mist as a designated pollutant.[a] Furthermore, fluorides and total reduced sulfur were designated primarily on the basis of adverse welfare effects. Specifically, fluorides are believed to damage vegetation and TRS has been shown to damage paint materials. In addition, TRS produces a foul odor which is considered an adverse welfare effect.

The five halogenated solvents specifically designated uner the NSPS for organic solvent cleaners were listed for several reasons. As ozone precursors (i.e., volatile organic compounds photochemically reactive), both perchloroethylene and trichloroethylene are subject to control based on the health criteria for ozone. EPA cited other possible health effects as additional reasons for designating these substances, including evidence of possible carcinogencity of perchloroethylene, trichloroethylene, methylene chloride, and 1,1,1-trichloroethane. Finally, both trichlorotrifluoroethane and 1,1,1=trichloroethane were cited as being implicated in the depletion of the stratospheric ozone layer which shields the earth from harmful ultraviolet radiation that increase skin cancer risks in humans. Of note is the fact that control of these five solvents was also proposed under Section III(d) for existing sources.

Exhibit 7-13 summarizes the criteria used by EPA to designate chemicals for regulation under Section 111.

STANDARDS

As previously discussed, the Clean Air Act explicitly specifies the criteria to be used to establish standards of performance. NSPS are to be based exclusively on the best adequately demonstrated technological system of continuous emission reduction, taking into account non-air quality health, environmental, and energy impacts, as well as other costs. The standards for designated pollutants are based on these statutory criteria.

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[a] Discussions with staff of the Office of Air Quality Planning and Standards, EPA.

EXHIBIT 7-13

DESIGNATION CRITERIA

Pollutant	Designation Criteria
Particulate Matter	Criteria Pollutant
Sulfur Dioxide	Criteria Pollutant
Nitrogen Oxides	Criteria Pollutant
Carbon Monoxide	Criteria Pollutant
Volatile Organic Compounds	Criteria Pollutant
Sulfuric Acid Mist	Health Effects
Fluorides	Welfare Effects
Total Reduced Sulfur	Welfare Effects
Perchloroethylene	Health Effects
Trichloroethylene	Health Effects
Methylene Chloride	Health Effects
Trichlorotrifluroethane	Health Effects
1,1,1-Trichloroethane	Health Effects

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*Proposed NSPS.

NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS--REGULATORY REVIEW

INTRODUCTION

This section summarizes the National Emission Standards for Hazardous Air Pollutants (NESHAPs) promulgated or proposed under the authority of Section 112 of the Clean Air Act in order to:

- identify the chemical substances which have been designated as hazardous air pollutants (HAPs) under Section 112;
- examine the criteria used by EPA to list chemical substances as hazardous air pollutants;
- review the emission standards for HAPs; and
- review the criteria used by EPA to set the emission standards.

OVERVIEW

Regulation under Section 112 is a two stage process: First, chemicals are designated and listed as hazardous air pollutants, and then, emission standards are issued.[1]

To be listed as a hazardous air pollutant, the statutory definition of the term "hazardous air pollutant" must apply to the chemical. According to Section 112, "the term hazardous air pollutant means an air pollutant to which no ambient air quality standard is applicable and which in the judgement of the Administrator causes, or contributes to, air pollution which may reasonably be anticipated to result in an increase in mortality or an increase in serious irreversible, or incapacitating reversible illness."

In the past, potential health hazards of a chemical have been brought to EPA's attention through scientific reports published in journals, other agencies investigating a particular chemical, and the Environmental Defense Fund asserting concern about a chemical. When EPA decides that the evidence of a particular chemical contributing to "air pollution which may reasonably be anticipated to result in an increase in mortality or an increase in serious irreversible, or incapacitating reversible illness," is sufficient, the Administrator will list the chemical as an HAP.

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[1] See Exhibit 7-14: Regulatory Chronology.

If EPA decides that an emission standard is necessary to protect the public health, it will propose a standard which provides "an ample margin of safety to protect the public health from such hazardous air pollutant."[2] If an emission standard is not feasible, EPA will issue "a design, equipment, work practice, or operational standard, or combination thereof which is adequate to protect the public health with an ample margin of safety."[3]

Although the definition of hazardous air pollutant in Section 112(a)(1) specifies the health effects which determine a hazardous air pollutant ("an air pollutant which may reasonably be anticipated to result in an increase in mortality or an increase in serious irreversible, or incapaciting reversible illness"), it allows EPA to decide what types of tests are sufficient to conclude that a chemical "causes or contributes" to air pollution, what types of tests provide enough information to conclude that a chemical presents a health hazard, how important other agency regulatory actions are, etc. In addition, under Section 112 the language, "ample margin of safety" allows some room for regulatory flexibility in determining appropriate emission standards.

DESIGNATION CRITERIA

EPA has designated and listed seven chemicals as hazardous air pollutants:

- Abestos
- Beryllium
- Mercury
- Vinyl Chloride
- Benzene
- Radionuclides
- Inorganic Arsenic

National Emission Standards have been promulgated or proposed for the first five chemicals listed, as of January 1, 1981. National Emission Standards for radionuclides and inorganic arsenic, as yet, had not been proposed by January 1, 1981. In addition, an air carcinogen policy was also proposed but not finalized.

Exhibit 7-14 presents a chronological review of the regulatory actions related to Section 112 of the Clean Air Act. The two-stage process of listing and promulgating emission standards is apparent from this regulatory chronology.

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[2] Clean Air Act, Section 112(b)(1)(B).

[3] Clean Air Act Section 112(e)(1).

EXHIBIT 7-14

REGULATORY CHRONOLOGY: NATIONAL EMISSIONS STANDARDS FOR HAZARDOUS AIR POLLUTANTS

Date	Regulatory Action	Federal Register Citation
March 31, 1971	Asbestos, Beryllium and Mercury Listed	36 FR 5931
December 7, 1971	Standards for Asbestos, Beryllium Beryllium Rocket Motor Firing, and Mercury Proposed	36 FR 23239
April 6, 1973	Final Standards for Asbestos, Beryllium, Beryllium Rocket Motor Firing, and Mercury	38 FR 8820
December 24, 1975	Vinyl Chloride Listed	40 FR 59477
December 24, 1975	Standard for Vinyl Chloride Proposed	40 FR 59532
October 21, 1976	Final Standard for Vinyl Chloride	41 FR 46560
June 8, 1977	Benzene Listed	42 FR 29332
October 10, 1979	Air Carcinogen Policy Proposed	44 FR 58642
October 10, 1979	Advance Notice of Proposed Rulemaking for Draft Generic Standards	44 FR 58662
December 27, 1979	Radionuclides Listed	44 FR 76738
April 8, 1980	Proposed Standard for Benzene -- Maleic Anhydride Plants	45 FR 26660
June 5, 1980	Arsenic Listed	45 FR 37886
December 18, 1980	Proposed Standard for Benzene -- Ethylbenzene Plants	45 FR 83448
December 19, 1980	Proposed Standard for Benzene Storage Vessels	45 FR 83952

Exhibit 7-15 summarizes the criteria used by EPA to list chemical substances as hazardous air pollutants, and the criteria relied on to set emission standards. The two primary criteria for listing chemicals are the health effects resulting from exposure and evidence of significant public exposure. As previously discussed, the health effects criterion is derived from the statutory language of Section 112 of the Clean Air Act. The significant public exposure criterion applies only to the most recently listed chemicals: Radionuclides, vinyl chloride, benzene, and inorganic arsenic. This is because EPA recently proposed an air carcinogen policy[4] which incorporates the significant public exposure criterion into EPA's regulatory policy for listing hazardous air pollutants.

EPA's proposed air carcinogen policy outlines how the agency will identify carcinogenic substances and how it will regulate them. The framework was proposed as Appendix C to Part 61 of Title 40 of the Code of Federal Regulations, and entitled, "National Emission Standards for Hazardous Air Pollutants: Policy and Procedures for Identifying, Assessing, and Regulating Airborne Substances Posing a Risk of Cancer." According to this proposed rule, a chemical substance would be judged to present a significant carcinogenic risk (and hence, be listed under Section 112 as an HAP) if:

> (1) it is believed to have a high probability of being a human carcinogen; and
>
> (2) there is evidence of significant public exposure via the ambient air from emissions of one or more categories of stationary sources.[5]

Since radionuclides and inorganic arsenic were listed as hazardous air pollutants after this air carcinogen policy was proposed, EPA relied on the policy to guide these two listing decisions. Consequently, evidence of significant public exposure was necessary before these most recently considered chemicals were listed as HAPs.

The specific criteria used by EPA to evaluate health impacts of the chemicals are listed in Exhibit 7-15. These criteria range from evidence of adverse health effects in laboratory animals to human occupational exposure data showing the health hazards of a chemical.

Exhibit 7-15 also lists the criteria used by EPA to establish emission standards for chemicals. It is clear from the table that the Agency sometimes relies on ambient monitoring data to set emission standards, and other times

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[4] See 44 FR 58642 (October 10, 1979).

[5] 44 FR 58654 (October 10, 1979), Proposed Rule as Appendix C, 40 CFR 61.

EXHIBIT 7-15

SUMMARY: LISTING CRITERIA AND EMISSIONS STANDARDS CRITERIA FOR HAZARDOUS AIR POLLUTANTS

	Asbestos	Beryllium	Mercury	Vinyl Chloride	Benzene	Radionuclides	Inorganic Arsenic
A. Listing Criteria							
1. Health Effects	x	x	x	x	x	x	x
epidemiological data (occupational)	x	x	x	x	x		x
epidemiological data (non-occupational)a/	x	x				x	x
animal bioassay data			x	x		x	x
mutagenicity data						x	
other regulations or agency actions	x	x		x	x	x	
no safe threshold					x	x	x
linear dose-response relationship						x	
2. Significant Exposure						x	x
B. Emissions Standards Criteria							
1. Ambient Monitoring Data				x	x	—b/	—b/
2. Estimated Emissions	x	x	x			—	—
dispersion estimates		x	x			—	—
production data estimates	x					—	—
3. Other Agency Standards	x	x				—	—
4. Extent of Human Exposure	x	x	x	x	x	—	—
additive exposure (cumulative effects)	x	x	x				
significant human exposure	x			x	x	—	—
5. Potency	x	x	x	x	x	—	—
no safe threshold	x			x	x	—	—
safety factor			x			—	—
6. Extent Emissions Can Be Controlled	x					—	—
availability of control technology	x			x	x	—	—
control equipment efficiency estimates	x				x	—	—
zero-emission level	x				x	—	—
best available control technology				x		—	—

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a/ Non-occupational data includes studies of human exposures other than occupational exposures.

b/ To date, no standards have been proposed for radionuclides or inorganic arsenic.

relies on estimates of emissions. Furthermore, when estimating emission levels, EPA bases these estimates on different methodologies. Both dispersion estimates and production data estimates are used to determine the level of emissions. Another consideration by EPA includes standards previously set by other agencies. EPA uses these other standards as guides when setting National Emission Standards.

The potency of the pollutant and the estimated extent of human exposure is important particularly for deciding which specific sources or categories of sources to regulate. The extent that emissions can be controlled is important to the setting of several emission standards. The availability of control technology and the efficiency of this control technology determine how well emissions can be controlled. Some emission standards are defined as the best available control technology as opposed to a specific concentration or output level.

In accordance with the Clean Air Act, EPA has set emission standards to provide an "ample margin of safety to protect the public health." To provide this level of protection EPA has relied on two standard-setting methods: One for threshold pollutants and one for carcinogens.[4] For threshold pollutants (i.e., pollutants with identifiable levels of exposure below which exposure would not be expected to result in adverse health effects), EPA sets emission standards "somewhere below the exposure level at which adverse health effects have been found to occur in empirical research." The standards provide an "ample margin of safety" because they are set at levels associated with minimal risk of adverse health effects. Standards for threshold pollutants are to be based solely on health effects criteria.

Carcinogens, on the other hand, have no identifiable adverse health effects thresholds and no exposure levels associated with zero risk of cancer. This poses a problem for the application of Section 112 to the regulation of airborne carcinogens. Two approaches were considered by EPA must determine the level of risk of cancer which provides "ample" protection of the public health:

(1) Set emission standards for carcinogens at zero to eliminate the risk of cancer incidence, or

(2) Permit residual risks.

The first approach was rejected by EPA because the Agency interpreted the phrase "ample margin of safety" as not requiring "the complete elimination of all risks." Several reasons were cited for this interpretation:

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[4] These methods are described in EPA's proposed air carcinogen policy, 44 FR 58659-61, October 10, 1979.

- If so intended, Congress would have explicitly stated in Section 112 that all risks from the emissions of carcinogens had to be eliminated, e.g., Delaney Clause of the Food and Drug Act.

- The consequences of zero-emission standards including possible widespread industry closures were not contemplated by Congress.

- The engineering term "margin of safety" does not imply a zero risk.

- Other public health statutes (Federal Insecticide, Fungicide and Rodenticide Act, Toxic Substances Control Act, Safe Drinking Water Act, Clean Water Act, and Occupational Safety and Health Act) permit considerations of factors other than risk in setting standards.

EPA adopted the second approach for applying the phrase "ample margins of safety" to the regulation of carcinogens.[7] EPA requires sources to use the "best available technology" to reduce cancer risks from emissions, and requires additional control measures only if residual risks are "unreasonable". To determine whether risks are "unreasonable" EPA considers such social and economic factors as:

- the benefits of the activity or substance producing the risk,

- the distribution of the benefits versus the distribution of the risks,

- the availability and possible environmental risks of substitutes for that substance or activity, and

- the cost of reducing the risks further.

In short, EPA focuses on reducing health risks from carcinogens, but considers additional factors in order to determine whether a given control level provides "ample" protection of public health.

CHEMICAL-BY-CHEMICAL ANALYSIS

This section of the paper examines each listed chemical in chronological order of their listing dates. The specific criteria used by EPA to list each chemical substance as a hazardous air pollutant are identified. In addition, the emission standards established by EPA, as well as the agency's rationale for setting the standards are discussed.

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[7] This approach has not yet been judicially resolved.

Asbestos (March 31, 1971)

The bases for EPA's selection of asbestos[8] as a hazardous air pollutant were several scientific studies showing the association between exposure to asbestos and the development of adverse health effects. Most of these scientific studies were based on occupational data; they related occupational exposure to asbestos and the incidence of bronchial cancer, asbestosis, and mesotheliomas (cancer of the membranes lining the chest and abdomen). A few scientific reports relied on non-occupational exposures in the neighborhood of asbestos sources to identify asbestos as a causal factor in the development of mesothelioma.

Standards and Criteria. The National Emission Standard for Asbestos requires that there be no visible emissions to the outside air from asbestos mills, selected manufacturing operations, the use of spray-on asbestos materials, demolition operations, the surfacing of roadways with asbestos tailings, the fabrication of certain structures, and insulation. The regulation allows owners and operators to elect an equipment-operational standard instead of complying with the no visible emission requirement.[9]

EPA chose the no visible emissions limit because the Agency saw no satisfactory means of establishing numerical concentrations or mass emission limits for asbestos. EPA believed the technology to be inadequate for measuring ambient asbestos concentrations and asbestos emissions.[10] Hence, a quantitative relationship between asbestos-caused illness and the dose which caused those illnesses was impossible to estimate. This uncertainty as to the shape and character of the dose-response curve in humans, made it impossible for EPA to determine the levels, if such levels exist, of asbestos exposure that would not be associated with any detectable risk. To ensure that the emission standard would provide an "ample margin of safety to protect the public health" from asbestos, EPA set a no visible emissions limit.

Although there are no satisfactory quantitative ambient asbestos or asbestos emissions data, scientific studies suggest that longer and more direct exposure to asbestos results in higher incidence of adverse health effects. This evidence led EPA to assume that the effects of asbestos inhalation are cumulative.

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[8] "'Asbestos' means actinolite, amosite, anthophyllite, chrysotile, crocidolite, and tremolite" (40 CFR 61.21(a)).

[9] 40 CFR 61.22(b).

[10] Preamble to the National Emission Standard for Asbestos, 38 FR 8820 (April 6, 1973).

Available scientific evidence does not indicate that levels of asbestos in most community air cause asbestosis. As a result, EPA concluded that it is not necessary to control all asbestos emissions. To determine which sources of asbestos emissions should be controlled, EPA relied on a National Academy of Sciences report on asbestos[11] which concluded: "Continued use (of asbestos) at minimal risk to the public requires that the major sources of man-made asbestos emissions into the atmosphere be defined and controlled."[12] Following the recommendation in the report, EPA focused on "major man-made sources"[13] in establishing the National Emission Standard for Asbestos.

In the absence of quantitative emission data, a 1970 national inventory of sources of asbestos[14] was instrumental in determining which major sources of asbestos emissions should be covered by the standard. This inventory, based on information obtained from production and reprocessing companies, included production figures, estimates of control equipment efficiency, and material balances; the inventory did not contain emission test results.

In determining which of the major sources of asbestos emissions should be covered by the standard, the Administrator also considered the effects other Federal regulations would have on the emissions from such sources and the proximity of such sources to the public.[15]

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[11] National Academy of Sciences, Asbestos (The Need for and Feasibility of Air Pollution Controls), Washington, 1971.

[12] Ibid. (emphasis added).

[13] Preamble to The National Emission Standard for Asbestos, 38 FR 8820 (April 6, 1973).

[14] National Inventory of Sources and Emissions - Cadmium, Nickel and Asbestos. Report by the Department of Health, Education, and Welfare, February 1970.

[15] Preamble to the National Emission Standard for Asbestos. 38 FR 8820. (April 6, 1973).

Beryllium (March 31, 1971)

In its determination that beryllium[16] was a hazardous air pollutant, EPA took into account the Atomic Energy Commission's (AEC) regulation of beryllium in 1949 where a limit for beryllium concentrations in community air was set at 0.01 ug of beryllium per cubic meter of air averaged over a 30-day period. Epidemiological data was considered which indicated that the effects of airborne beryllium materials on human health included both acute and chronic lethal inhalation effects, as well as skin and conjunctral effects. This data relied primarily on occupational exposures to beryllium. The Beryllium Registry,[17] which records proven cases of beryllium-related disease, includes 45 cases of non-occupationally incurred diseases out of 820 total listed cases of disease. The Administrator determined that sources of beryllium emissions into the atmosphere should be controlled in order to protect human health from beryllium-related diseases.

Standards and Criteria. Retrospective studies of the concentrations of beryllium that resulted in human cases of chronic beryllium disease from non-occupational exposures concluded that the lowest concentration which produced disease was greater than 0.01 ug/m^3 and probably less than 0.10 ug/m^3.

The lack of any mechanism for the total elimination of beryllium body burdens, resulted in EPA assuming that exposures to beryllium are additive.

The Atomic Energy Commission's beryllium concentration limit served as a guideline for EPA's standards. There have been no reported cases of chronic beryllium disease as a result of community exposure since the implementation of the AEC standard. The Committee on Toxicology of the National Academy of Sciences concluded that the AEC guideline limit represents a safe level of exposure. Accordingly, EPA determined that sources of beryllium emissions into the atmosphere should be controlled to insure that ambient concentrations of beryllium do not exceed 0.01 ug/m^3 as a 30-day average.

The beryllium standard covers all stationary sources which could result in ambient beryllium concentrations in excess of 0.01 ug/m^3. These include:

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[16] "'Beryllium' means the element beryllium. Where weights or concentrations are specified, such weights or concentrations, apply to beryllium only, excluding the weight or concentration of any associated elements" (40 CFR 61.31(a)). Associated elements are defined as loosely bound elements in The Condensed Chemical Dictionary by Gessner G. Hawley (8th Edition, New York: Van Nostrand Reinhold Co., 1971, p. 83).

[17] Massachusetts General Hospital, U.S. Beryllium Case Registry, Boston.

(a) Extraction plants, ceramic plants, foundries, incinerators, and propellant plants which process beryllium ore, beryllium, beryllium oxide, beryllium alloys,[18] or beryllium-containing waste; and,

(b) Machine shops which process beryllium, beryllium oxides, or any alloy when such alloys contain more than 5 percent beryllium by weight.[19]

The National Emission Standard for Beryllium requires that emissions to the atmosphere from stationary sources shall not exceed 10 grams of beryllium over a 24-hour period. This level of emissions was determined quantitatively through dispersion estimates as the level which would protect against the occurrence of 30-day average ambient concentrations exceeding 0.01 ug/m^3.

The beryllium standard allows those sources which have demonstrated to EPA's satisfaction that they can meet and have met the ambient concentration (0.01 ug/m^3 for a 30-day average), to comply with the standard by use of ambient monitoring to insure that the 0.01 ug/m^3 30-day average is never exceeded.[20]

Mercury (March 31, 1971)

Animal (rat) data and human occupational exposures were the basis for EPA's decision to list mercury[21] as a hazardous air pollutant. Both sources of data indicated that exposure to metallic mercury vapors causes central nervous system injury and kidney damage. The animal experiments indicated a risk of accumulation of mercury in critical systems upon prolonged exposure with a potential, for example, for selective brain damage.

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[18] "'Beryllium alloy' means any metal to which beryllium has been added in order to increase its beryllium content and which contains more than 0.1 percent beryllium by weight."

[19] 40 CFR 61.30(a) and 61.30(b).

[20] Separate National Emission Standards were issued for beryllium rocket motor firing. (40 CFR Subpart D). Rocket-motor test sites must meet the emission limits of 75 microgram minutes per cubic meter of air within the limits of 10 to 60 minutes, accumulated during any 2 consecutive weeks. If combustion products from the firing of beryllium propellant are collected in a closed tank, emissions from such tank shall not exceed 2 grams per hour and a maximum of 10 grams per day.

[21] "'Mercury' means the element mercury, excluding any associated elements (i.e., elements which are loosely bound to mercury), and includes mercury in particulates, vapors, aerosols, and compounds."

Standards and Criteria. To determine what level of mercury emissions would provide "an ample margin of safety to protect the public health," EPA first considered an epidemiological evaluation of risks. From this evidence, EPA concluded that prolonged exposure to 100 micrograms mercury per cubic meter of air involves a definite risk of mercury intoxication.

EPA relied on further epidemiological analyses to determine the "safe" level of exposure to mercury. One epidemiological study investigated several exposures of mercury poisoning in Japan. The study concluded that four micrograms of methylmercury (which is considered to be by far the most hazardous mercury compound) per kilogram of body weight per day would result in the intoxication of a sensitive adult; application of a safety factor of 10[22] yielded an acceptable exposure of about 30 micrograms per day for a 70-kilogram person. EPA believes that this "safe" level of exposure will protect against genetic lesions and poisoning of the fetus and children.

Since the exposure to mercury is assumed to be additive, the EPA considered the airborne burden of mercury together with the water and food-borne burdens. Epidemiological studies estimate that from average diets (including water and food) over a considerable period, mercury intakes of 10 micrograms per day may be expected. In order to restrict total intake to the "safe" level of 30 micrograms per day, the average mercury intake from air would have to be limited to 20 micrograms per day. After assuming that average inhalation is 20 cubic meters of air per day, the air could contain an average daily concentration of no more than 1 microgram of mercury per cubic meter. This is the method used by EPA to estimate the "safe" exposure level to airborne mercury.

The mercury standard regulates those sources which have been found to emit mercury in a manner that could cause the ambient concentration to exceed the inhalation effects limits of one microgram per cubic meter. The sources which qualify are mercury ore processing facilities, mercury cell chlor-alkali plants, sludge incineration plants, sludge drying plants, and any plants that process wastewater treatment plant sludges.

The permissible levels of emissions are:

(1) 2,300 grams of mercury per day from mercury ore processing facilties and mercury cell chlor-alkali plants, and

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[22] Preamble to the National Emission Standard for Mercury, 38 FR 8824, (April 6, 1973).

(2) 3,200 grams of mercury per 24-hour period from sludge incineration plants, sludge drying plants, and any combination of these that process water waste treatment plant sludges.[23]

These levels of emissions were derived from dispersion estimates as the levels which would protect against the violation of an average daily ambient concentration of one microgram per cubic meter.

Vinyl Chloride (December 24, 1975)

The EPA based its determination that vinyl chloride[24] is a hazardous air pollutant on data gathered during a 1974 EPA study to investigate whether federal regulation of atmospheric emissions of vinyl chloride from manufacturing facilities was needed. The EPA study included animal bioassay and epidemiological data, which strongly indicated that vinyl chloride caused or contributed to the development of angiosarcoma, other cancers and noncarcinogenic disorders in people with occupational exposure and in animals with experimental exposure. The study served as the basis for EPA's conclusion that vinyl chloride met the specifications of the definition of "hazardous air pollutant" in Section 112 of the Clean Air Act.[25]

Animal bioassay experiments showed vinyl chloride to cause cancer in both sexes of three species of rodents by the inhalation route. Angiosarcoma of the liver was observed in rat, hamster, and mice bioassays. Furthermore, these animal studies showed a multiple cancer risk from vinyl chloride, i.e. tumors in the liver, brain, lungs, kidneys, and mammary glands. In addition, bioassay studies indicated the potential of vinyl chloride to be a chemical mutagen and teratogen.

Epidemiological studies of occupational exposure to vinyl chloride (mainly among workers involved directly in polyvinyl chloride production) have strongly implicated vinyl chloride as a human chemical carcinogen which causes tumors in many different sites. Other manifestations in humans include acro-osteolysis and liver dysfunction.

There are no dose-response data, and no absolute proof of health risks at the concentrations of vinyl chloride found in the ambient air. As a result, EPA relied on "reasonable extrapolations" from the animal bioassay and occupational findings to conclude that present ambient levels of vinyl chloride are hazardous.[26]

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[23] 40 CFR 61.52(a) and (b).

[24] Vinyl chloride is not defined in the regulations.

[25] Preamble to the Proposed National Emission Standard for Vinyl Chloride, 40 FR 59532 (December 24, 1975).

Also cited by EPA as rationale for designating vinyl chloride as an HAP were:

- a study completed in April 1970 by the Ad Hoc Committee on the Evaluation of Low Levels of Environmental Chemical Carcinogens entitled, "The Evaluation of Environmental Carcinogens";
- several court decisions including: (1) Environmental Defense Fund, Inc. v. Environmental Protection Agency, 510 F.2d 1292 (D.C. Cir., 1975); (2) Environmental Defense Fund, Inc. v. Ruckleshaus, 142 U.S. App. D.C. 74, 439 F.2d 584 (1971); and (3) Society of the Plastics Industry, Inc. v. Occupational Safety and Health Administration, 509 F.2d 1301 (1975); and
- OSHA's vinyl chloride standard promulgated in 1974.

Standards and Criteria. EPA considered the extent of human exposure to vinyl chloride when establishing the emission standard. Data obtained in 1974 from U.S. plants that produce or process vinyl chloride indicated that approximately 100 million kg of vinyl chloride are emitted to the atmosphere annually. The majority of these emissions are from ethylene dichloride, vinyl chloride and polyvinyl chloride plants.

An ambient monitoring program conducted by EPA in 1974-1975 was cited as part of the rationale for regulating vinyl chloride under the authority of Section 112 of the Clean Air Act. Results of this ambient monitoring program suggest that 4.6 million people may be exposed to higher than average vinyl chloride concentrations. The lack of dose-response data and EPA's assumption that no level of exposure to a chemical carcinogen is toxicologically insignificant for humans were instrumental in EPA's decision to reduce exposure levels to vinyl chloride; by reducing exposure levels, EPA intended to reduce substantially the risk that severe illness and death would occur in the future as a result of present and prolonged community exposure to vinyl chloride.[27]

EPA considered regulating air emissions of vinyl chloride under Section 109 (National Ambient Air Quality Standards) rather than under Section 112 of the Clean Air Act. This alternative was rejected by EPA because vinyl chloride is a localized problem and Section 109 is more appropriate for regulating pollutants whose presence in the ambient air is ubiquitous. Also, the National Ambient Air Quality Standards/State Implementation Plan process does not provide the expedited means of control to be used for a hazardous air pollutant.[28]

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[26] Ibid., 40 FR 59533 (December 24, 1975).

[27] 40 FR 59533 (December 24, 1975).

To determine what level of emission control should be required, EPA considered the economic, health and environmental impacts of a complete prohibition of all vinyl chloride emissions, as well as the availability of control technology. EPA concluded that setting zero emission limits would be neither desirable nor necessary under Section 112. Section 112(b)(1)(B) states: "The Administrator shall establish any such standards at the level which in his judgment provides an ample margin of safety to protect the public from such hazardous air pollutants."[29] In the judgment of EPA's Administrator, setting emission standards that require emission reduction to the lowest level achievable by use of the best available control technology provides "an ample margin of safety to protect the public health" from vinyl chloride.[30] This interpretation of Section 112 has never been judicially tested.

EPA recognizes that consideration of technology in standard setting is not explicitly provided for under Section 112. However, the Agency believes that Congress did not intend to impose the costs associated with complete emission prohibition (i.e., widespread industry closure and costs "grossly disproportionate" to benefits) in every case involving a non-threshold pollutant.[31] According to EPA, "the purpose of the standard is to minimize the risk to the public health by setting emission limits which will reduce emissions to the level attainable with the best available control technology for each emission source in ethylene dichloride, vinyl chloride, and polyvinyl chloride plants."[32] This type of emission standard will result in different ambient air concentrations at different plants due to variations in plant size and configurations.

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[28] Preamble to the Proposed National Emission Standards for Vinyl Chloride, 40 FR 59534 (December 24, 1974).

[29] Clean Air Act, Section 112(b)(1)(B).

[30] Preamble to the Proposed National Emission Standard for Vinyl Chloride, 40 FR 59534 (December 24, 1975).

[31] This discussion is from the Preamble to the Proposed Standard for Vinyl Chloride, 40 FR 59534, (December 24, 1975).

[32] Ibid., 40 FR 59535-36.

Two criteria were used by EPA for making technical decisions involved in developing a standard on the basis of "best available control technology." These criteria were:

(1) The control technology must be in use in one or more plants in the chemical industry and be generally adaptable for use at the plants subject to the standard within the time allowed for compliance under Section 112, and

(2) Costs were considered only when they were grossly disproportionate to the emission reduction achieved.[33]

In general, the emission standard limits the concentration of vinyl chloride to 10 ppm in all exhaust gases discharged to the atmosphere from any equipment used in ethylene dichloride purification, vinyl chloride formation and/or purification, and from each polyvinyl chloride reactor. More specific emission standards were established for oxychlorination reactors in ethylene dichloride plants, and certain other emission sources.

Benzene (June 8, 1977)[34]

The Environmental Defense Fund brought the issue of listing benzene as a hazardous air pollutant to EPA's attention. The EDF petitioned EPA to list benzene following the Occupational Safety and Health Administration's proposed rule to reduce allowable workplace exposure levels of benzene.

The decision to list benzene as an HAP was based on studies of workers in a variety of industries and occupations; particularly influential was the April 1977 National Institute for Occupational Safety and Health study indicating high levels of leukemia in exposed workers.

Numerous occupational studies provide evidence of human health hazards resulting from prolonged inhalation exposure to benzene. However, these studies involve occupational exposure to benzene at levels higher than those found in the ambient air. Nevertheless, EPA concluded that "ambient exposures [to benzene] may constitute a cancer risk and should be reduced."[35] For this reason, EPA decided to list benzene as a hazardous air pollutant which may cause or contribute to irreversible or incapacitating adverse health effects.

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[33] Preamble to the Proposed National Emission Standard for Vinyl Chloride, 40 FR 59536 (December 24, 1975).

[34] Benzene is not defined in the proposed regulations. See listing notice 42 FR 29332 (June 8, 1977).

[35] Ibid.

Standards and Criteria. As of January 1, 1981, EPA had proposed three emission standards for sources of benzene: (1) maleic anhydride plants, (2) ethylbenzene and styrene plants, and (3) storage vessels.[36]

To determine what degree of control should be required for benzene, EPA considered the availability of control technology, estimates of control equipment efficiency, and the relative risk to the public. When evaluating the relative risk to the public, EPA noted that benzene is produced and used in large quantities throughout the United States, and that a large number of people are routinely exposed to measurable concentrations of benzene in the ambient air. The principal sources of benzene emissions are chemical manufacturing facilities, petroleum refineries, gasoline storage and handling facilities, coke ovens, and automobiles. Maleic anhydride plants account for 35 percent of all stationary source emissions of benzene, and are by far the largest source of benzene emissions in the chemical manufacturing industry. In addition, when EPA ranked all stationary source categories according to estimates of cancer incidence and risk to the most exposed population, maleic anhydride plants ranked high.[37] Similar rationales support the proposed standards for ethylbenzene plants and storage vessels.

As of January 1, 1981, no final benzene National Emission Standard has been promulgated.

Radionuclides (December 27, 1979)

Studies of human populations which conclusively show that sufficient exposure to radiation increases the risk of many different kinds of cancer, served as the basis for EPA's listing of radionuclides[38] as a hazardous air pollutant. Extensive studies in experimental animals, especially rodents, and studies of cell cultures were cited by EPA as important in their selection of radionuclides as an HAP. These animal and cell studies show that ionizing radiation can cause many types of mutations; extrapolations of mutation rates calculated in these studies formed the basis for estimating the genetic (hereditary) impact of ionizing radiation in humans.

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[36] See 45 FR 26662 (April 18, 1980), 45 FR 83448 (December 18, 1980), and 45 FR 83952 (December 19, 1980), respectively. A standard for fugitive emissions was proposed on January 5, 1981, see 46 FR 1165.

[37] Preamble to the Proposed National Emission Standard for Benzene Emissions from Maleic Anhydride Plants, 45 FR 26662 (April 18, 1980).

[38] "Among the radionuclides included are those defined by the Atomic Energy Act as source material, special nuclear material, and byproduct material" (44 FR 76738), December 27, 1979).

Since there is no conclusive evidence of the effects of very low doses of radiation on human populations, the Agency assumed that the effects of low doses of radiation are proportional to the dose received. This assumption involves the linear extrapolation of large doses to estimate the human health impact from low dose exposure.

As provided in EPA's recently proposed rules for regulating airborne carcinogens, (Appendix C, 40 CFR 61), an important criteria for listing is the evidence of *significant public exposure* to radionuclides because of emissions into the atmosphere.[39] To determine the extent of human exposure to radionuclides and the magnitude of risk, EPA compiled a list of the amount of radionuclides released into the atmosphere for each major category of facility known to use such materials. The Agency estimated the radiation dose to the nearest individuals and to the regional population. Using these doses, EPA estimated the additional lifetime fatal cancer risk to individuals, and the total number of fatal cancers induced in the surrounding population. Recognizing that these estimates are highly uncertain, EPA concluded that the potential risk from doses as large as those received from many of the facilities is unnecessarily high (45 FR 76738).

In summary, EPA determined that exposure to radionuclides increased the risk of human cancer and genetic damage; in addition, EPA concluded that public exposure to radionuclides was significant. Thus, radionuclides constitute hazardous air pollutants within the meaning of the Clean Air Act.

Standards and Criteria. National Emission Standards for radionuclides have not been issued yet. However, as provided in EPA's recently proposed rules for regulating airborne carcinogens (44 FR 58642 (October 10, 1979)), EPA will base all decisions on setting standards for radionuclide emissions on detailed risk assessments and complete regulatory options analyses considering the following factors: a detailed examination of sources of emissions of radionuclides into air, the risk caused by these emissions, the costs and effectiveness of emission control technologies, the benefits of the activities causing the emissions, the relationships between who is receiving the benefits versus who is required to accept the risks, and the possibility of using substitutes to reduce emissions.[40]

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[39] Proposed Rule Appendix C, 40 CFR 61, 44 FR 58654 (October 10, 1979).

[40] "NESHAP: Policy and Procedures for Identifying, Assessing, and Regulating Airborne Substances Posing a Risk of Cancer," 44 FR 58642 (October 10, 1979).

Inorganic Arsenic (June 5, 1980)

The decision to list inorganic arsenic[41] as a hazardous air pollutant is based on EPA's judgment that:

(1) there is a high probability that exposure to inorganic arsenic causes cancer in humans; and

2) there is significant public exposure to inorganic arsenic that is emitted into the air by stationary sources.[42]

The identification of inorganic arsenic as a probable human carcinogen is based on animal bioassay data and epidemiological evidence. This evidence includes occupational exposure data causally relating inorganic arsenic and the incidence of cancer. Furthermore, studies of the health impact of inorganic arsenic on communities surrounding industrial sources of arsenic emissions show excess cancer mortalities among humans living near the sources.

A 1977 EPA-initiated exposure study identified multiple stationary sources of arsenic, showed that large numbers of people are exposed to localized ambient concentrations of arsenic many times the national average concentration, and clearly related such concentrations to identifiable stationary sources. This EPA-initiated exposure study was instrumental in EPA's conclusions that inorganic arsenic causes cancer in humans, and there is significant public exposure to airborne inorganic arsenic. It should be noted that the requirements for listing a suspected carcinogen specified in EPA's proposed rule, "Policy and Procedures for Identifying, Assessing, and Regulating Airborne Substances Posing a Risk of Cancer" (44 FR 58642, October 10, 1979), have been met by inorganic arsenic.

EPA believes that it is scientifically infeasible to establish safe threshold levels for airborne carcinogens.[43] The Agency has taken the position that the absence of conclusive proof that substances shown to be carcinogenic at high levels are also carcinogenic at lower exposure levels is not relevant to a decision to list the substance as a hazardous air pollutant.** Hence, it is assumed in this listing decision that there is no safe threshold for inorganic arsenic.

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[41] Inorganic arsenic, not organic arsenic, is listed as a hazardous air pollutant (45 FR 37886, June 5, 1980). Inorganic arsenic is not defined in the regulations.

[42] Ibid.

[43] 44 FR 58642 (October 10, 1979).

Standards and Criteria. National Emission Standards for inorganic arsenic have not been proposed as of January 1, 1981.

** *Ibid*.

MOTOR VEHICLE AND AIRCRAFT EMISSION STANDARDS-- REGULATORY REVIEW

MOTOR VEHICLE EMISSIONS

As required by Section 202 of the Clean Air Act, EPA promulgated motor vehicle emission standards for carbon monoxide, hydrocarbons, oxides of nitrogen, and particulate matter: 40 CFR 86, Control of Air Pollution from New Motor Vehicles and New Motor Vehicle Engines.

Oxides of nitrogen are defined in the regulations as "the sum of the nitric oxide and nitrogen dioxide contained in a gas sample as if the nitric oxide were in the form of nitrogen dioxide" (40 CFR 86.077-2). EPA excludes some oxides of nitrogen such as nitrous oxide in its definition of "oxides of nitrogen". EPA explains that the emission standard for "oxides of nitrogen" has always been based only on measurement of nitric oxide, and nitrogen dioxide because all other oxides are emitted in quantities too small to measure without extreme difficulty.[1] National Ambient Air Quality Standards apply only to nitrogen dioxide. Carbon monoxide, hydrocarbons, and particulates are not defined in these regulations.

As EPA has extended the Motor Vehicle Emission Standards to cover motorcycles and other types of moving sources, the criteria for determining the level of the standard has been the contribution of emissions from these vehicles to ambient concentrations of carbon monoxide, hydrocarbons, nitrogen oxides, and particulates. If the emissions contribute substantially to the allowable ambient air concentrations and impede the achievement of National Ambient Air Quality Standards, then the emissions are regulated under 40 CFR 86: Control of Air Pollution from New Motor Vehicles and New Motor Vehicle Engines.

In accordance with Section 202, these standards are based upon the "best available control technology", giving appropriate consideration to "the cost of applying such technology within the period of time available to manufacturers and to noise, energy, and safety factors associated with the application of such technology." (Emphasis added).

AIRCRAFT EMISSIONS

The same chemicals are regulated by aircraft emission standards as are regulated by motor vehicle emission standards with one exception. The substances common to both regulations are:

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[1] Ford Motor Co. v. EPA, 604 F.2d 685 (D.C. Cir. 1979).

(1) Hydrocarbons

(2) Carbon Monoxide

(3) Oxides of Nitrogen

The difference between these regulations is that particulate matter is regulated only by motor vehicle emission standards, while smoke is regulated only by aircraft emission standards.

Smoke is defined in the regulations as "the matter in exhaust emissions which obscures the transmission of light" (40 CFR 87.1(a)(27)). Oxides of nitrogen means "the sum of the amounts of the nitric oxide and nitrogen dioxide contained in a gas sample as if the nitric oxide were in the form of nitrogen dioxide" (40 CFR 87.1(a)(29)). Carbon monoxide and hydrocarbons are not defined in these regulations.

FUEL AND FUEL ADDITIVES--REGULATORY REVIEW

INTRODUCTION

This section summarizes the Fuel and Fuel Additive regulations promulgated under the authority of Section 211 of the Clean Air Act in order to:

- identify the chemical substances which have been designated for registration;
- examine the criteria used by EPA to regulate fuels and fuel additives under Section211; and
- review the regulations of fuels and fuel additives.

The statutory review of Section 211 describes the two requirements for fuels and fuel additives authorized by the Clean Air Act: Registration and regulation. The regulations promulgated under Section 211, similarly, are twofold. 40 CFR 79 applies to the registration requirement, while 40 CFR 80 deals with the control and/or prohibition provisions. Exhibit 7-16 summarizes the chronology of regulations promulgated under Section 211.

BACKGROUND

In order to understand the various regulations and the purpose of controlling these substances, it is useful to know some general characteristics of fuels and fuel additives.[1]

Motor vehicle fuels essentially are mixtures of various hydrocarbons, additives, and impurities. Exhibit 7-17 indicates the variety of hydrocarbon compounds contained in gasoline; these hydrocarbon compounds can be grouped into three general types: aromatics, olefins, and paraffins. Aromatics and olefins contribute to the formation of photochemical smog. Exhibit 7-18 identifies the many common additives contained in gasoline, and their primary functions.

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[1] "Fuel means any material which is capable of releasing energy or power by combustion or other chemical or physical reaction." (40 CFR 79.2(c))

"Additive means any substance, other than one composed solely of carbon and/or hydrogen, that is intentionally added to a fuel named in the designation (including any added to a motor vehicle's fuel system) and that is not intentionally removed prior to sale or use" (40 CFR 79.2(e)).

EXHIBIT 7-16

REGULATORY CHRONOLOGY

Date	Regulatory Action	Federal Register Citation
February 23, 1972	Availability of Unleaded Gasoline Regulations Proposed	37 FR 3882
January 10, 1973	Availability of Unleaded Gasoline Regulations Promulgated	38 FR 1258
December 6, 1973	Control of Lead Additives in Gasoline Regulations Promulgated	38 FR 33734
December 12, 1974	Availability of Unleaded Gasoline Regulations Amended	39 FR 43281
November 7, 1975	Registration of Fuels and Fuel Additives Regulations Promulgated	40 FR 52009
September 28, 1976	Lead Phase-Down Schedule Revised	41 FR 42675
September 12, 1979	Lead Phase-Down Schedule Revised	44 FR 53144
March 7, 1980	Lead Phase-Down Schedule Revised	45 FR 14854
June 2, 1980	Lead Phase-Down Schedule Revised	45 FR 37197
August 18, 1980	Lead Phase-Down Schedule Revised	45 FR 55134

When gasoline is burned in an internal combustion engine, carbon monoxide, nitrogen oxides, and unburned hydrocarbons are emitted to the atmosphere. In response to Motor Vehicle Emission Standards promulgated under the authority of Section 202 of the Clean Air Act, vehicles were equipped with emission control systems to reduce the emissions of carbon monoxide, nitrogen oxides, and hydrocarbons. These emission control systems require the use of lead-free gasoline, so EPA established regulations providing for the availability of unleaded gasoline.

In addition to the apparent need to furnish unleaded gasoline for new cars with lead-sensitive catalytic reactors, EPA determined that, based on public health considerations, it was necessary to reduce lead particulate emissions from older vehicles which use leaded gasoline.[2] Lead is added to gasoline to increase the fuel octane number, and thus, prevent engine knocking. Because the Clean Air Act does not authorize EPA to establish emission standards for in-use vehicles, EPA promulgated regulations to phase-down the lead additive[3] content of leaded gasoline, thereby reducing lead emissions.

EPA registers fuels and additives to obtain information on fuel and additive composition before the emission products of such materials develop into problems possibly requiring control or prohibition.[4]

40 CFR Part 79.30 identifies the following fuels and additives to be registered under Section 211:

(1) Leaded and unleaded motor vehicle gasoline (except motorcycle gasoline) and diesel fuel, grades 1-D and 2-D.

(2) All additives produced or sold for use in motor vehicle gasoline and/or motor vehicle diesel fuel.

REGULATION OF FUELS AND FUEL ADDITIVES: 40 CFR 80

40 CFR 80 contains the rules for the control and/or prohibition of fuels and additives used in motor vehicles and motor vehicle engines. The designation of substances for regulation under this part is based on two criteria: The emission product of a fuel or additive:

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[2] "Leaded gasoline means gasoline which is produced with the use of any lead additive or which contains more than 0.05 grams of lead per gallon or more than 0.005 grams of phosphorus per gallon" (40 CFR 80.2(g)).

[3] "Lead additive means any substance containing lead or lead compounds" (40 CFR 80.2(e)).

[4] Preamble to Registration of Fuels and Fuel Additives, 40 FR 52009, November 7, 1975.

(1) "will endanger the public health", or

(2) will impair "to a significant degree" the performance of a motor vehicle emission control device. (40 CFR 80.1(a))

As discussed in the Background section, two separate regulations of fuel and fuel additives have been promulgated in 40 CFR 80: (1) availability of lead-free gasoline, and (2) control of lead additives. These regulations are described in the next sections.

Availability of Lead-Free Gasoline. On February 23, 1972 (37 FR 3882), EPA proposed regulations requiring the general availability by July 1, 1974 of essentially lead-free gasoline. This regulation was based on EPA's determination that emission products of lead in motor vehicle gasolines "impair to a significant degree the performance of emission control systems that include catalytic converters which motor vehicle manufacturers are developing to meet 1975-76 motor vehicle emission standards." These emissions control systems are intended to control nitrogen oxides, carbon monoxides, and hydrocarbons.[5]

EPA's objective in establishing these regulations was to prevent the detriment to air quality that would occur if a significant number of catalytic converters were damaged by using leaded gasoline in vehicles with lead-sensitive emission control systems.

In accordance with the Clean Air Act, Section 211(c)(2)(A), EPA considered all available scientific and economic data prior to this proposal. In addition, the Agency took into account a cost-benefit analysis comparing motor vehicle emission control devices or systems. Finally, EPA published a paper entitled "Effects of Reduced Use of Lead in Gasoline on Vehicle Emissions and Photochemical Reactivity" which indicates that requiring general availability of lead-free gasoline will not cause the use of any other fuel or fuel additive that will produce emissions which will endanger the public health or welfare to the same or greater degree.

Regulations providing for the availablity of unleaded gasoline to protect emission control devices were promulgated on January 10, 1973 (38 FR 1258). Because of the way unleaded gasoline is defined,[6] these regulations apply to phosphorus in gasoline, as well as to lead in gasoline.

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[5] Preamble to the Proposal for Regulation of Lead and Phosphorous Additives in Motor Vehicle Gasoline, 37 FR 3882, February 23, 1972.

[6] "Unleaded gasoline means gasoline containing not more than 0.05 grams of lead per gallon and not more than 0.005 grams of phosphorus per gallon" (40 CFR 80.2(g)).

Control of Lead Additives. The second regulation of fuels and fuel additives was promulgated by EPA on December 6, 1973. This rule establishes Federal standards limiting the use of lead additives in gasoline (38 FR 33734), because automobile exhaust emissions of lead particles "pose a threat to public health" (36 FR 1486, January 30, 1971).

In making the determination that lead emissions endanger public health, EPA considered the three factors required by Section211:

(a) all relevant medical and scientific evidence,

(b) other technologically or economically feasible means, and

(c) fuel and additive substitutions.

Health Rationale. The Agency's evaluation that there is a health basis for reducing the use of lead in gasoline is presented in a paper entitled "EPA's Position on the Health Implications of Airborne Lead." The medical and scientific evidence cited by EPA in the determination that lead emissions pose health risks are summarized in Exhibit 7-17.

Feasibility Criterion. In accordance with the Clean Air Act, Section 211(c)(2)(A), EPA is required to consider whether it would be more economically or technologically feasible to provide for the public health by means of emission standards for new vehicles under Section 202 of the Act (New Motor Vehicle Emission Standards) than by means of reducing gasoline lead content. Section 202 applies only to new vehicles; the Clean Air Act does not permit EPA to establish emission standards for in-use vehicles. As a result, older vehicles would continue to use leaded gasolines. The Agency believed it unlikely that new motor vehicles could be equipped with emission control devices for lead ("lead-traps") prior to the 1976 model year. In the meantime, the public would be exposed to levels of airborne lead related to adverse health effects. Additionally, lead-traps cannot adequately protect the lead sensitive emission control systems on new vehicles, because lead-traps are not capable of trapping all of the lead emitted. For these reasons, EPA concluded that providing for the protection of public health by means of Section 202 alone was not feasible.

Substitutes. Under Section 211, EPA is required to assure that the control of lead additives will not result in the use of other gasoline components or additives which would endanger public health to the same or greater degree than lead additives. If the use of lead in gasoline is restricted, refiners must use greater quantities of blending stocks with high aromatic hydrocarbon (e.g., benzene, toluene, xylene) concentrations, or substitute anti-knock additives to increase gasoline octane levels (see Exhibit 7-16). EPA considered the health effects of increasing the aromatic hydrocarbon content of gasoline, and increasing the use of manganese additives which function as anti-knock additives; the Agency also considered the impact

EXHIBIT 7-17

MEDICAL AND SCIENTIFIC EVIDENCE THAT LEAD EMISSIONS POSE HEALTH RISKS

(1) The aggregate contribution of lead from all sources including food, water, air, leaded paint and dust, poses a significant threat to health.

(2) Lead from gasoline accounts for approximately 90 percent of airborne lead.

(3) Exposure to lead among the general population is widespread.

(4) Preliminary data show that concentrations of airborne lead found in major cities can affect blood lead levels.

(5) Lead-contaminated dust and dirt from motor vehicle exhaust are hypothesized to be important sources contributing to excessive lead exposures associated with subclinical and clinical effects in children.

(6) Clinical symptoms resulting from high lead exposure in children are known to be associated with permanent neurologic damage.

(7) Physiologically significant biochemical changes, impairment of fine motor functions, and altered behavior have been observed to occur in children with excessive exposures below clinical toxicity.

of these regulations on particulate emissions. The results of these investigations are summarized below.

First, implementation of these regulations is projected to result in a five to seven percent increase in the average aromatics content of gasoline. On the basis of evidence presented in the paper entitled "Effects of Reduced Use of Lead in Gasoline on Vehicle Emissions and Photochemical Reactivity,"[7] EPA asserted that increasing the aromatic hydrocarbon content of gasoline would not significantly impact automobile emissions reactivity and the formation of photochemical smog. Although aromatic hydrocarbons do facilitate the formation of photochemical smog, increasing the aromatic hydrocarbon content of gasoline would be offset by a decrease in the olefin content of gasoline (olefin also facilitates the formation of photochemical smog). The end result would be that automobile emissions reactivity, and thus, the formation of photochemical smog, would not be significantly impacted.

Increasing the aromatic hydrocarbon content of gasoline would increase polynuclear aromatic hydrocarbon (PNA) emissions. PNA (e.g., fluorene, napthalene, pyrene) are hydrocarbon emission products which are carcinogenic (38 FR 33738, December 6, 1973) and present risks to public health. According to EPA estimates, implementation of these lead regulations would increase automobile polynuclear aromatic hydrocarbon emissions by about 2 percent and total PNA emissions by approximately 0.04 percent. EPA considered this increase "negligible" (38 FR 33738, December 6, 1973). Consequently, the Agency concluded that these regulations would not endanger public health to a greater degree than lead emissions by increasing the aromatic hydrocarbon content of gasoline.

Second, EPA investigated the health effects of increasing the use of manganese additives, since manganese may be used as a partial replacement for lead in gasoline. Occupational exposure studies have indicated that airborne manganese at sufficiently high levels of exposure can cause damage to the central nervous system and can cause manganese pneumonia. However, the dosages required to produce these adverse effects are several orders of magnitude above those that would be present in the ambient air. Hence, EPA concluded that the use of manganese additives would not pose as significant a risk to health as that from lead additives.

EPA did not address the chronic effects of low-level manganese exposures when the lead additive regulations were introduced in 1973. However, the Clean Air Act was amended on November 16, 1977 to include controls on manganese additives to gasoline after considering the chronic effects of low-level exposures. Section 211(f)(2) of the amended Act prohibits the introduction into commerce of "any gasoline which contains a concentration of manganese in excess of .0625 grams per gallon of fuel."

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[7] By Dr. A. P. Altshuller, February 1972.

Third, EPA determined that these regulations would have a favorable impact on particulate emissions. Because lead additives account for a major portion of exhaust particulates, the use of fuel without lead additives would substantially decrease particulate emissions. In light of the adverse health effects resulting from particulate matter, this regulation can be viewed as protecting the public health from particulates as well as lead emissions.

Lead Phase-Down Schedule. In summary, the regulations promulgated on December 6, 1973 were designed to reduce lead usage from base 1971 by 60-65 percent. The reduction schedule, which uses total gasoline pool averaging, prescribes reducing the lead content in leaded gasoline over a 4-year period to 0.5 grams per gallon by January 1, 1979. EPA recognized that the precise level of lead additive content associated with adverse health effects cannot be stated with certainty. However, the Agency established the promulgated reduction schedule on the basis that it is "reasonable" from the standpoint of protection of public health and from the standpoint of economic and technological feasibility.[1]

The promulgated reduction schedule is:

January 1, 1975 - - - - - - - - - - - - - - 1.7 grams of lead per gallon
January 1, 1976 - - - - - - - - - - - - - - 1.4 grams of lead per gallon
January 1, 1977 - - - - - - - - - - - - - - 1.0 grams of lead per gallon
January 1, 1978 - - - - - - - - - - - - - - 0.8 grams of lead per gallon
January 1, 1979 - - - - - - - - - - - - - - 0.5 grams of lead per gallon

EPA determined that total pool averaging is the "fairest workable mechanism for accomplishing the necessary reduction in lead usage" because it does not discourage production of unleaded gasoline, and is the most neutral system in its effect upon industry marketing decisions. A quarterly averaging period was selected because EPA found that this length of time permitted optimum refining flexibility while also permitting the attainment of necessary reductions in lead usage.

Impact of Gasoline Supply Situation. In order to remove lead additives from gasoline and retain the octane rating necessary to meet the octane requirements of motor vehicle engines, refiners must produce more high octane components as lead substitutes. The amount of high octane components which can be produced depends on the availability of refining facilities. The lead time necessary to install additional refining facilities is about 2 to 3 years (41 FR 42675, September 28, 1976). If refiners do not install the additional refining facilities, they will not be able to produce enough high octane components to produce their anticipated levels of gasoline and meet the lead phase-down schedule. Alternatively, they must cut back on the production of all gasoline in order to comply with the lead phase-down schedule. In this way, the lead phase-down schedule could constrain the supply of gasoline.

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[1] Preamble to Regulation of Fuel and Fuel Additives, 38 FR 33734, December 6, 1973.

To avoid a gasoline shortage, EPA promulgated an amendment to the regulations on September 28, 1976 (41 FR 42675) establishing a revised lead reduction schedule. The intent of the amendment was to achieve the desired reduction of lead in gasoline as expeditiously as practicable for protection of public health without causing a gasoline shortage.[1] The lead phase-down regulations were relaxed once again on September 12, 1979 (44 FR 43144) as a result of the interruption of crude oil supplies from Iran and the overall tightness in gasoline supplies. In response to an over-production of unleaded gasoline, EPA revoked the unleaded gasoline requirements for the quarter beginning January 1, 1980 and ending March 31, 1980 and for the quarter beginning April 1, 1980 and ending June 30, 1980 (45 FR 37197), as well as for the quarter beginning July 1, and ending September 30 (45 FR 55134).

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[1] Preamble to Amendment of 40 CFR 80, 41 FR 42675, September 28, 1976. (Emphasis added.)

COMPREHENSIVE ENVIRONMENTAL RESPONSE, COMPENSATION, AND LIABILITY ACT OF 1980-
STATUTORY REVIEW

INTRODUCTION

In late 1980, Congress passed the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, commonly known as "Superfund." The legislation, a compromise negotiated during the lameduck session, deals with some of the problems posed by the hazards of chemical waste and its disposal. Because it was passed so recently, there have been no regulations promulgated and no reported court cases dealing with it. Therefore, this statutory review will be brief and will be confined to the language of the statute itself and the legislative history of the earlier versions of the bill.

In the next section, a broad overview of the statute and its operations will be presented. The final section will deal with the specific issues that are of particular concern in this review, what is a "hazardous substance" or a "pollutant or contaminant" and what substances are taxed by Superfund.

OVERVIEW OF THE STATUTE

The major elements of Superfund are: certain notification requirements, the establishment of a Hazardous Substance Response Trust Fund, authority for removal and remedial actions, and the liability imposed. Each of these areas will be discussed in this section. It should be kept in mind, however, that since the most important area here is the substances involved (discussed in the next section), this discussion will cover only the highlights of the statute.

Notification: Superfund requires that those in charge of a vessel or facility[1] from which a release[2] of the required quantity of a hazardous substance[3] occurred report the release to the National Response Center.[4] Similarly, any persons owning, operating, or transporting hazardous substances to a facility at which the substances have been stored, treated, or disposed of without the appropriate permits are required to notify the Environmental Protection Agency (EPA) of the existence of such a facility.[5] In addition, records on disposal facilities must generally be kept for fifty years.[6]

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[1] Both "vessel" and "facility" are broadly defined in Section 101 (Section references are to the Act). For instance, "facility" includes motor vehicles, rolling stock, and aircraft.

[2] Broadly defined in Section 101(22).

[3] Defined in Section 101(14) and discussed in detail in the next section.

[4] Section 103(a).

Hazardous Substances Response Trust Fund: Superfund establishes a Fund[7] to be used by the President to respond to releases of hazardous substances,[8] to reimburse response costs properly paid by other parties, to pay claims for injury to or destruction or loss of natural resources,[9] and to pay certain other expenses.[10] The Fund consists of

> (1) moneys received from taxes levied upon crude oil received at a refinery in the United States or used in or exported from the United States, upon petroleum products entering the United States, and upon the sale of 42 enumerated chemicals[11] and
>
> (2) appropriations of up to $220,000,000 over a five-year period.[12]

Responses: The Act provides that the President shall revise the National Contingency Plan to include a section on "procedures and standards for responding to releases of hazardous substances, pollutants, and contaminants."[13] Response under Superfund includes both cleanup ("removal") and more permanent action taken to prevent additional harm ("remedial action").[14] The President may respond, consistent with the National Contingency Plan, whenever there is a release or a "substantial threat" of a release of any hazardous substance or "any pollutant or contaminant which may present an imminent and substantial danger to the public health or welfare" and the responsible party has not properly responded and will not so respond.[15]

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[5] Section 103(c).

[6] Section 103(d).

[7] Section 221.

[8] See the next paragraph for more detail on responses.

[9] Natural resources is fairly broadly defined, but includes only those resources controlled by federal, state, local, or foreign governments. See Section 101(16).

[10] Section 111.

[11] Section 211. A discussion of how these substances were chosen is presented in the next section.

[12] Section 221(b)(2).

[13] Section 105. The definition of "pollutant or contaminant" is discussed in the next section.

Liability: The liability provisions of Superfund are broad. Owners and operators of vessels or facilities (including facilities at which hazardous substances were disposed of), persons who arranged for the disposal, treatment, or transportation of such substances, and persons who accepted hazardous substances for transport are liable. Liability extends to the costs of responding (including both removal and remedial action incurred by any person consistent with the National Contingency Plan) and damages for injury to, destruction of, or loss of natural resources. The defenses available are quite limited.[16]

The discussion to this point has covered the main provisions of Superfund, namely, when and by whom notice must be given of releases and improper storage, treatment, and disposal of hazardous substances; what the Hazardous Substances Response Trust Fund may be used for and how it will be funded; when the President is authorized to respond; and who is liable for what costs and damages. With this background, the more significant topics of how "hazardous substance" and "pollutant or contaminant" are defined and how the substances upon which fees are charged to finance the Fund were chosen can be meaningfully discussed. This will be the subject of the next section of this review.

DESIGNATION CRITERIA

This section will be divided into three parts: (1) hazardous substance, (2) pollutant or contaminant, and (3) substances taxed. In each part, the discussion will center on the statutory language and its intended meaning or purpose as revealed in the legislative history.

Hazardous Substance

For the purposes of this statutory review, the definition of hazardous substance is the most significant provision in Superfund. Hazardous substances are important in Superfund both because the release of certain quantities of them must be reported and because the Act authorizes the President to respond to releases or threat of releases of such substances.[17] Hazardous substances are defined in Section 101(14):

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[14] Section 101(25) defines "response," Section 101(23), "removal," and Section 101(24), "remedial action."

[15] Section 104(a).

[16] Section 107.

> (14) "hazardous substance" means (A) any substance designated pursuant to section 311(b)(2)(A) of the Federal Water Pollution Control Act, (B) any element, compound, mixture, solution, or substance designated pursuant to section 102 of this Act, (C) any hazardous waste having the characteristics identified under or listed pursuant to section 3001 of the Solid Waste Disposal Act (but not including any waste the regulation of which under the Solid Waste Disposal Act has been suspended by Act of Congress), (D) any toxic pollutant listed under section 307(a) of the Federal Water Pollution Control Act, (E) any hazardous air pollutant listed under secton 112 of the Clean Air Act, and (F) any imminently hazardous chemical substance or mixture with respect ot [sic] which the Administrator has taken action pursuant to section 7 of the Toxic Substances Control Act.
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> The term does not include petroleum, including crude oil or any fraction thereof which is not otherwise specifically listed or designated as a hazardous substance under subparagraphs (A) through (F) of this paragraph, and the term does not include natural gas, natural gas liquids, liquefied natural gas, or synthetic gas usable for fuel (or mixtures of natural gas and such synthetic gas).

From this definition, it can be seen that there are two basic mechanisms in the Act for designating a substance as hazardous. The first is by the terms of the statute itself. Substances falling within the terms of Section 101(14)(A) and Section 101(14)(C) through (F) are automatically hazardous. Each of these subsections will be discussed briefly.

Section 101(14)(A): Under Section 311(b)(2)(A) of the Federal Water Pollution Control Act,[18] some 297[19] substances have been designated as hazardous substances. For a detailed discussion, see the regulatory review of the Clean Water Act.

[17] The President is also authorized to respond to releases or threatened releases of certain "pollutants or contaminants", as discussed in the next part of this section.

[18] 33 USCA 1321(b)(2)(A).

[19] 40 CFR §116.

Section 101(14)(C): Pursuant to Section 3001 of the Solid Waste Disposal Act,[20] a waste is listed as hazardous if it fulfills one of these requirements:

> (1) EPA has determined that it meets one of the statutory requirements of hazardous waste in Section 1004(5) of that Act;
>
> (2) EPA has determined that it can be fatal in low doses or is otherwise capable of causing or significantly contributing to an increase in serious irreversible, or incapacitating reversible, illness; or
>
> (3) EPA has determined that it contains designated toxic constituents, unless it is not capable of posing a substantial present or potential hazard to human health or the environment.[21]

For more information, refer to the statutory and regulatory reviews of the Resource Conservation and Recovery Act.

Section 101(14)(D): Under Section 307(a) of the Federal Water Pollution Control Act,[22] 65 categories of chemicals have been designated as toxic pollutants.[23] For a list of these, see Exhibit 6 of the regulatory review of the Clean Water Act.

Section 101(14)(E): There are presently seven chemicals that have been designated as hazardous pursuant to Section 112 of the Clean Air Act:[24] asbestos, beryllium, mercury, vinyl chloride, benzene, inorganic arsenic, and radionuclides.[25] For additional detail, see the regulatory review of the Clean Air Act.

Section 101(14)(F): At the present time, there are no chemicals with respect to which EPA has taken action under Section 7 of the Toxic Substances Control Act.[26] See the regulatory review of that Act.

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[20] 42 USCA 6921.

[21] S. Rep. No. 96-848, 96th Cong., 2nd Sess. 27-28 (1980).

[22] 33 USCA 1317(a).

[23] 40 CFR §401 (Toxic Pollutant List).

[24] 42 USCA 7412.

[25] 40 CFR §61.

[26] S. Rep. No. 96-848, 96th Cong., 2nd Sess. 27 (1980). Section 7 is 15 USCA 2606.

In each instance, reference must be made to the relevant statute to determine what substances are hazardous under Superfund. The legislative history noted, "As substances are added to these lists they would be automatically designated as hazardous substances for purposes of" Superfund.[27] Although not specifically mentioned here, it would be reasonable to assume that if substances are deleted from these lists, they would no longer be hazardous under this provision of the Act.

The other mechanism for designating substances as hazardous under Superfund is given in Section 101(14)(B)--substances so designated by EPA pursuant to Section 102. Section 102 provides:

> Sec. 102.(a) The Administrator shall promulgate and revise as may be appropriate, regulations designating as hazardous substances, in addition to those referred to in section 101(14) of this title, such elements, compounds, mixtures, solutions, and substances which, when released into the environment may present substantial danger to the public health or welfare or the environment, and shall promulgate regulations establishing that quantity of any hazardous substance the release of which shall be reported pursuant to section 103 of this title. The Administrator may determine that one single quantity shall be the reportable quantity for any hazardous substance, regardless of the medium into which the hazardous substance is released.
>
> (b) Unless and until superseded by regulations establishing a reportable quantity under subsection (a) of this section for any hazardous substance as defined in section 101(14) of this title, (1) a quantity of one pound, or (2) for those hazardous substances for which reportable quantities have been established pursuant to section 311(b)(4) of the Federal Water Pollution Control Act, such reportable quantity, shall be deemed that quantity, the release of which requires notification pursuant to section 103(a) or (b) of this title.

In commenting upon the earlier Senate version[28] of this section Section 3(a)(2), the Senate Committee on Environment and Public Works stated:

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[27] S. Rep. No. 96-848, 96th Cong., 2nd Sess. 24 (1980). (Often referred to hereafter as Senate Committee Report).

[28] This version, S. 1480, gave the powers of Section 102 to the President rather than to the Administrator of EPA.

> Section 3(a)(2) authorizes the President to designate as hazardous substances those compounds, elements, mixtures, and solutions which may present substantial danger to public health and welfare and the environment. This provision essentially authorizes the President to augment the existing lists of hazardous substances derived from existing statutes (see, section 2(b)(13) (A), (B), (C), (D), and (E)). The language of this provision has a lower threshold for designation than that currently in place in section 311(b)(2) of the Clean Water Act. This is intended to afford the President broad discretion in designating substances which may adversely affect public health or the environment.[29]

Section 102 does more than merely allow EPA to designate additional substances as hazardous. It permits EPA to set the amount of hazardous substance the release of which must be reported under Section 103. Until EPA sets other quantities, Section 102(b) establishes reportable quantities of one pound or, where applicable, the reportable quantity established pursuant to Section 311(b)(4) of the Federal Water Pollution Control Act. The Senate Committee Report had this to say about the setting of reportable quantities:

> The provision intentionally omits from the requirement to determine 'reporting' quantities any reference to harm or hazard. A single quantity is to be determined for each hazardous substance, and this single quantity requires notification upon release into any environmental medium. It would be virtually impossible to determine a single quantity applicable to all media while at the same time linking such quantity to any subjective concept of harm.
>
> It is essential that such quantities be relatively simple for those subject to notification requirements to understand and comply with. Since releases in such quantities trigger notification requirements, but do not, in and of themselves, give rise to other liabilities under this Act, the Presidents' [sic] broad discretion to select quantities will not unfairly burden those persons subject to the Act.
>
> In determining reportable quantities under this paragraph, the President may consider any factors deemed relevant to administering the reporting requirements or the President's other responsibilities under this Act. Administrative feasibility and practicality should be primary

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[29] Emphasis added. Senate Committee Report at 28.

> factors. In addition, the President may revise such regulations from time to time if under-reporting or over-reporting is occurring under existing regulations.[30]

It should be noted that the Act as finally passed permits, but does not *require*, establishment of a single quantity for each hazardous substance regardless of the medium, but the reasons given by the Committee why such a single quantity might be valuable are still valid.

Several additional points concerning these reportable quantities should be made. The first is that the wording of Section 102(a) would apparently allow EPA to establish reportable quantities for *all* hazardous substances under the statute (including those which are automatically hazardous under Superfund), not just for those substances designated hazardous by EPA pursuant to that section. An earlier Senate version seemed to allow the President to set these quantities only for those substances he determined to be hazardous pursuant to this section.

Another point which may be of greater interest is that the reportable quantity of one pound (applicable to those substances not covered by Section 311(b)(4) of the Federal Water Pollution Control Act) does not contain any time period over which it must be released. There is no requirement, for instance, that the release occur in one incident or within, say, 24 hours. Appropriate regulations can rectify this problem, but until that time, there is significant uncertainty in this area.[31]

One final issue that deserves mention here is the potential differences in reportable quantities under Superfund and other statutes involving the same substances. Initially, the reportable quantities established for substances pursuant to Section 311(b)(4) of the Federal Water Pollution Control Act are adopted for Superfund, but the reportable quantities of other substances are set at one pound. These are *all* subject to change by regulation. Thus, even for those substances affected by Section 311 of the Federal Water Pollution Control Act, Superfund may eventually have different reportable quantities under different statutes. This will work against the simplicity and lack of undue burden of which the Senate Committee on Environment and Public Works spoke as quoted above at footnote 30.

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[30] *Ibid*. at 29.

[31] It should be noted that, pursuant to Section 305, Congress has the authority to veto regulations promulgated under Superfund. If Congress exercises this authority, it could delay the date that effective regulations eliminate this uncertainty.

Pollutant or Contaminant

Hazardous substances, discussed above, are important in Superfund because their release or threatened release triggers both the notice requirements of Section 103 and the response authority of Section 104. The release or threatened release of a "pollutant or contaminant," however, triggers only the response authority of Section 104. In addition, such release or threatened release only authorizes the President to act when it "may present an imminent and substantial danger to the public health or welfare."[32/]

Section 104(a)(2) provides this definition of "pollutant or contaminant":

> For the purposes of this section, 'pollutant or contaminant' shall include, but not be limited to, any element, substance, compound, or mixture, including disease-causing agents, which after release into the environment and upon exposure, ingestion, inhalation, or assimilation into any organism, either directly from the environment or indirectly by ingestion through food chains, will or may reasonably be anticipated to cause death, disease, behavioral abnormalities, cancer, genetic mutation, physiological malfunctions (including malfunctions in reproduction) or physical deformations, in such organisms or their offspring.
>
> The term does not include petroleum, including crude oil and any fraction thereof which is not otherwise specifically listed or designated as hazardous substances under section 101(14)(A) through (F) of this title, nor does it include natural gas, liquefied natural gas, or synthetic gas of pipeline quality (or mixtures of natural gas and such synthetic gas).

In an earlier Senate version of the bill, a similar, though not quite as broad,[33/] definition was included as part of the definition of hazardous substance. As in the present Act, notification requirements generally did not extend to releases of substances coming only under this part of the definition. The Senate Committee Report stated:

[32/] Section 104.

[33/] It was not quite as broad because it did not use the phrase "shall include, but not be limited to. . . ." S. 1480, Section 2(13)(G).

> This generic definition is included because hazardous substances characteristically are not included on a governmental list until after they have demonstrated their danger by killing or injuring people or causing significant environmental damages. The actual listing of a substance lags behind release and exposure by years and sometimes decades. This happens even though the persons responsible for manufacturing or handling the substances usually know, either through experience or scientific studies, of the substance's dangerous propensities.
>
> Examples of substances added to lists only after they caused harm, even though there was reason to know of their dangerous qualities earlier, include asbestos, kepone, and organic mercury. Some substances have not been included on one of the relevant lists even after they have, in fact, caused grievous injuries.
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> * * *
>
> Subparagraph (G) describes substances which are harmful to humans and includes them within the scope of S. 1480 whether they are included on a regulatory list or not. The definition was intentionally made broad in order to assure that any substance or agent which causes disease in humans, whether it is an element, chemical, pathogen, or mixture, is included. Of course, if a substance is determined as 'hazardous' only by virtue of section 2(b)(13)(G)--that is, it meets the subparagraph (G) definition, but is not a designated hazardous substance under subparagraphs (A) through (F)--the consequences under this bill are less than if it has been on one of the lists.[34]

The present definition of pollutant or contaminant would seem to serve the same purpose.

Substances Taxed

Superfund is primarily financed through fees paid on the sale or use of a number of chemicals. The chemicals themselves ae not necessarily hazardous, but somewhere in the chain of production, sale, or use of these chemicals, a hazardous substance is generated. The Senate Committee Report said this about why this fee system and these chemicals were chosen:

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[34] S. Rep. No. 96-848, 96th Cong., 2nd Sess. 29, 30 (1980).

Financing the Fund primarily from fees paid by industry is the most equitable and rational method of broadly spreading the costs of past, present and future releases of hazardous substances among all those industrial sectors and consumers who benefit from such substances. The concept of a fund financed largely by appropriations was not adopted. A largely appropriated fund establishes a precedent adverse to the public interest--it tells polluters that the longer it takes for problems to appear, the less responsible they are for paying the consequences of their actions, regardless of the severity of the impacts. Too often the general taxpayer is asked to pick up the bill for problems he did not create; when costs can be more appropriately allocated to specific economic sectors and consumers, such costs should not be added to the public debt.

The fee system was adopted after extensive investigation of alternatives. This fee system provides the best balance of equity, rapid implementation, legal defensibility, administrative simplicity, and a minimum of any adverse economic and environmental impacts. The fees are imposed at the beginning of the commercial chain of production, distribution, consumption, and disposal of hazardous substances. The fee is assessed on substances which are either hazardous themselves or are the basic building blocks (primary petrochemicals, inorganic raw materials and petroleum oil) used to make almost all major hazardous substances.

By collecting a fee at the beginning of the producton cycle, this fee system uses the efficiency of the marketplace to automatically and broadly distribute the risks associated with chemicals through fees on all industrial sectors in the chain of production, transportation, use and disposal of hazardous substances. This is a more effective mechanism than distributing risks through the rules and regulations of a Federal agency and it is fully consistent with the spirit of regulatory reform.

The 46[35] substances subject to the fee meet at least two or more of the following criteria: (i) they are inherently hazardous or hazardous in a number of forms

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[35] In the final legislation, 42 chemicals (almost all of which were on the Senate list of 46) plus crude oil and petroleum products are taxed.

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(intermediates or final products), (ii) they are hazardous in some form if released, (iii) hazardous wastes are generated in producing them or their intermediate or final products, (iv) they are capable in one or more forms of increasing the hazardous potential of other substances; and (v) they are produced in significant quantities. A fee may attach to a product even though it is itself environmentally benign, since earlier in the chain of production, distribution, consumption and disposal it used a hazardous substance or later in the chain it will be used to generate a hazardous substance.[16]

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[16] S. Rep. No. 96-848, 96th Cong., 2nd Sess. 72-73 (1980).